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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte VISHNU VARDHAN MAKKAPATI,
NEVENKA DIMITROVA, RANDEEP SINGH, and SUNIL KUMAR

Appeal 2019-005485
Application 13/979,908
Technology Center 1600

Before DONALD E. ADAMS, FRANCISCO C. PRATS, and
TAWEN CHANG, *Administrative Patent Judges.*

CHANG, *Administrative Patent Judge.*

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1–4, 6, 8, 9, and 11–18. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as Koninklijke Philips N.V. Appeal Br. 3.

STATEMENT OF THE CASE

The Specification states that voluminous genomic sequence data requires "significant amounts of storage capacity" and "high-end computational devices for its analysis." Spec. 1:30–32. The Specification further states that, moreover, "most of the genomic sequence data obtained during whole genome sequencing runs will rather hamper than improve . . . diagnostic possibilities" for a professional "who is concerned with a specific clinical question and would like to have focused information with regard to identified symptoms or suspected diseases." *Id.* 2:4–8.

According to the Specification, therefore, "[t]here is . . . a need for a method allowing a time and resource preserving handling of a patient's genomic data." Spec. 2:9–10. Further according to the Specification, "[t]he present invention relates to a method for processing a subject's genomic data comprising (a) obtaining a subject's genomic sequence; (b) reducing the complexity and/or amount of the genomic sequence information; and (c) storing the genomic sequence information of step(b) in a rapidly retrievable form." *Id.* at 1:5–8.

CLAIMED SUBJECT MATTER

The claims are directed to a method for processing a subject's genomic sequence data. Claim 1 is illustrative:

> 1. A method for processing a subject's genomic sequence data, the method comprising:
>
> obtaining the subject's genomic sequence data using a next generation sequencing apparatus, the genomic sequence data comprising coverage of at least 90% and including signature data comprising a plurality of genetic or genomic variations specific to one or more disorders, diseases, predispositions for a disorder or a disease, or risk factors for development of a disease or disorder;

using a processor configured to reduce complexity included in the subject's genomic sequence data by: (i) aligning the subject's genomic sequence data with a reference sequence comprising signature data, (ii) detecting the subject's genomic sequence data comprising signature data, and (iii) removing, from the subject's genomic sequence data, data other than the signature data to generate reduced complexity genomic sequence data;

storing the reduced complexity genomic sequence data in a storage structure comprising annotated database entries in a differential DNA storage structure format, wherein the storage structure encodes acquisition time information associated with the reduced complexity genomic sequence data and allows for locally unrestrained access to the reduced complexity genomic data and associated time information and other medical data; and

providing access to the reduced complexity genomic data and associated time information and other medical data in a clinical environment, thereby facilitating clinical decision-making pertaining to the subject;

wherein the signature data comprises two or more of a missense mutation, nonsense mutation, single nucleotide polymorphism (SNP), copy number variation (CNV), splicing variation, variation of a regulatory sequence, small deletion, small insertion, small indel, gross deletion, gross insertion, complex genetic rearrangement, inter chromosomal rearrangement, intra chromosomal rearrangement, loss of heterozygosity, and insertion of repeats and deletion of repeats.

Appeal Br. 35 (Claims App.).

REJECTION(S)

A. Claims 1–4, 6, 8, 9, and 11–18 are rejected under 35 U.S.C. § 101 as being directed to an abstract idea without significantly more. Ans. 3.

B. Claims 1, 8, 14, and 15 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Chang,[2] Gatawood,[3] Sherry,[4] Metzker,[5] and Kane.[6] Final Act. 10–11.

C. Claims 2, 13, and 16–18 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Chang, Gatawood, Sherry, Metzker, Kane, and Greenman.[7] Final Act. 14.

D. Claims 3, 4, and 12 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Chang, Gatawood, Sherry, Metzker, Kane, and Bollet.[8] Final Act. 15.

E. Claim 6 is rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Chang, Gatawood, Sherry, Metzker, Kane, and Langmead.[9] Final Act. 16.

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[2] H. Chang et al., *Seq-SNPing: Multiple-Alignment Tool for SNP Discovery, SNP ID Identification, and RFLP Genotyping*, 13 OMICS: J. INTEGRATIVE BIOLOGY 253 (2009).
[3] Gatawood et al., US 2008/0077607 A1, published Mar. 27, 2008.
[4] S. T. Sherry et al., *dbSNP: the NCBI Database of Genetic Variation*, 29 NUCLEIC ACIDS RES. 308 (2001).
[5] M. L. Metzker, *Sequencing Technologies – the Next Generation*, 11 NATURE REVIEWS GENETICS 31 (2010).
[6] Kane et al., WO 2009/108802 A2, published Sep. 3, 2009.
[7] C. Greenman et al., *Pattern of Somatic Mutation in Human Cancer Genomes*, 446 NATURE 153 (2007).
[8] M. A. Bollet, *High-Resolution Mapping of DNA Breakpoints to Define True Recurrences Among Ipsilateral Breast Cancers*, 100 JNCI 48 (2008).
[9] Ben Langmead et al., *Ultrafast and Memory-Efficient Alignment of Short DNA Sequences to the Human Genome*, 10 GENOME BIOLOGY R25 (2009)

F. Claim 9 is rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Chang, Gatawood, Sherry, Metzker, Kane, and Rhodes.[10] Final Act. 17.

G. Claim 11 is rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Chang, Gatawood, Sherry, Metzker, Kane, and Hwang.[11] Final Act. 17.

OPINION

A. Subject matter eligibility rejection under § 101

1. Issue

The Examiner concludes that "[t]he process of claim 1, but for the limitation of using a generic computer processor, falls within the mental processes grouping of abstract ideas." Ans. 3. The Examiner concludes that this judicial exception is not integrated into a practical application because independent claim 1 comprises only the additional elements of "use of a computer processor, inputting data, storing data, . . . outputting data," and "using a next-generation sequencing procedure to produce sequence data." *Id.* at 5–6. The Examiner finds that "[t]he recited computer functions are functions of a generic computer that do not represent an improvement in the functioning of a computer or any other practical application of the recited

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[10] D. R. Rhodes, *Oncomine 3.0: Genes, Pathways, and Networks in a Collection of 18,000 Cancer Gene Expression Profiles*, 9 NEOPLASIA 166 (2007).

[11] D. G. Hwang & Phil Green, *Bayesian Markov Chain Monte Carlo Sequence Analysis Reveals Varying Neutral Substitution Patterns in Mammalian Evolution*, 101 PNAS 13994 (2004).

judicial exception," and "[t]he sequencing steps are data gathering that does not represent a practical application of the recited judicial exception." *Id.*

The Examiner further finds that "[t]he claims do not include additional elements that are sufficient to amount to significantly more than the judicial exception," because the additional elements of claim 1 are merely "conventional functions and components of a generic computer." Ans. 6.

Appellant argues that the claims are not directed to an abstract idea because they are "directed to a specific improvement in: (1) improved storage efficiency for a database and (2) retrieval of relevant portions of a subject's whole genome sequence, which facilitates clinical decision-making pertaining to the subject." Appeal Br. 19. More specifically, Appellant argues that the claims relates to "storing the [relevant] portions [of a subject's whole genome] in a manner that allows for unrestrained access in a clinical setting." *Id.* Appellant argues that "[d]ue to the reduced complexity of the [stored] genetic data, . . . memory and storage space required for storing the genetic information can be reduced drastically[,]" and "the matching/analysis of the data is significantly faster." *Id.* at 19, 21–22.

The issue with respect to this rejection is whether a preponderance of the evidence supports the Examiner's conclusion that claim 1 recites a judicial exception to patent eligibility, without significantly more.

2. Analysis

We analyze this case under the framework set forth by the Supreme Court in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), and applied by our reviewing court in *Ariosa Diagnostics,*

Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015). As the *Ariosa* court explained:

> In *Mayo* . . . , the Supreme Court set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. First, we determine whether the claims at issue are directed to a patent-ineligible concept. . . . If the answer is yes, then we next consider the elements of each claim both individually and "as an ordered combination" to determine whether additional elements "transform the nature of the claim" into a patent-eligible application. . . . The Supreme Court has described the second step of this analysis as a search for an "inventive concept"—i.e., an element or combination of elements that is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself."

Id. at 1375.

Mayo Step One: Whether Claim 1 Is Directed to Abstract Idea

We begin with the first step of the *Mayo* test, namely whether a claim is "directed to" a patent-ineligible concept.

On January 7, 2019, the Director of the USPTO issued the "2019 Revised Patent Subject Matter Eligibility Guidance" ("Revised Guidance"), which provides further details regarding how the Patent Office analyzes patent-eligibility questions under 35 U.S.C. § 101. Revised Guidance, 84 Fed. Reg. 50–57 (Jan. 7, 2019). Under the Revised Guidance, the first step of the *Mayo* test (i.e., Step 2A of the Revised Guidance) is "a two-pronged inquiry." *Id.* at 54. In prong one, we evaluate whether the claim recites a judicial exception, such as laws of nature, natural phenomena, or abstract ideas. *Id.* The Revised Guidance explains that the abstract idea exception

includes the following groupings of subject matter, when recited as such in a claim limitation(s) (that is, when recited on their own or per se):

> (a) Mathematical concepts—mathematical relationships, mathematical formulas or equations, mathematical calculations;
> (b) Certain methods of organizing human activity—fundamental economic principles or practices (including hedging, insurance, mitigating risk); commercial or legal interactions (including agreements in the form of contracts; legal obligations; advertising, marketing or sales activities or behaviors; business relations); managing personal behavior or relationships or interactions between people (including social activities, teaching, and following rules or instructions); and
> (c) Mental processes—concepts performed in the human mind (including an observation, evaluation, judgment, opinion).

Id. at 52 (footnotes omitted). If the claim recites a judicial exception, the claim is further analyzed under prong two, which requires "evaluat[ion of] whether the claim recites additional elements that integrate the exception into a practical application of that exception."

First Prong of Revised Guidance Step 2A

With respect to the first prong of Step 2A of the Revised Guidance, we agree with the Examiner that claim 1 recites a patent-ineligible abstract idea. In particular, claim 1 recites a method of processing a subject's genomic data, the method comprising

> using a processor configured to reduce complexity included in the subject's genomic sequence data by: (i) aligning the subject's genomic sequence data with a reference sequence comprising signature data, (ii)

> detecting the subject's genomic sequence data comprising signature data, and (iii) removing, from the subject's genomic sequence data, data other than the signature data to generate reduced complexity genomic sequence data.

Appeal Br. 35 (Claims App.). Each of steps (i)–(iii) above, however, are mental processes, i.e., concepts that may be performed in the human mind or by a human using pen and paper. *See* Revised Guidance, 84 Fed. Reg. at 52; *see also Cybersource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1373 (explaining that "[i]t is clear that unpatentable mental processes are the subject matter of [the] claim" because "[a]ll of [the] method steps can be performed in the human mind, or by a human using a pen and paper"). Such mental processes are not patentable. *Mayo*, 566 U.S. at 71; *see also Genetic Technologies, Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1378 (Fed. Cir. 2016) (holding that "[t]he term 'to detect the allele' (in the sense of examining the non-coding region to detect an allele in the coding region) is a mental process step, . . . because it merely sets forth a routine comparison that can be performed in the human mind").

Second Prong of Revised Guidance Step 2A

The second prong of Step 2A asks whether the claims as a whole integrate the judicial exception into a practical application of the exception. Revised Guidance, 84 Fed. Reg. at 54. We find that claim 1 does not recite additional elements that integrate the recited abstract idea into a practical application of the idea.

The elements of claim 1 in addition to mental processes are: (1) "obtaining the subject's genomic sequence data using a next generation sequencing apparatus, the genomic sequence data comprising coverage of at

least 90% and including signature data . . . "; (2) a processor; (3) "storing the reduced complexity genomic sequence data in a storage structure comprising annotated database entries in a differential DNA storage format, wherein the storage structure encodes acquisition time information . . . and allows for locally unrestrained access to . . . data"; and (4) "providing access to the . . . data in a clinical environment . . . ." Appeal Br. 35 (Claims App.).

The limitations relating to "obtaining the subject's genomic sequence data" and "storing the reduced complexity genomic sequence data" in the recited manner do not integrate the recited abstract mental processes into a practical application, because they merely "add[] insignificant extra-solution activity to the judicial exception." 84 Fed. Reg. at 55. In particular, the limitations relating to obtaining the subject's genomic sequence merely gather data for practicing the abstract mental process. *Cybersource*, 654 F.3d at 1372 (explaining that, "even if some physical steps are required to obtain information from the database" regarding credit card transactions for purposes of fraud detection, "such data-gathering steps cannot alone confer patentability"); *see also Mayo*, 566 U.S. at 1297–1298 (holding that "[p]urely 'conventional or obvious' '[pre]-solution activity'," such as a step of determining the level of a recited metabolite, "is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law) (alteration original).

Likewise, the limitations regarding "storing the reduced complexity genomic sequence data" are insignificant post-solution activity even if the claim specifies particular additional information (*e.g.*, acquisition time information) to be stored. In *Electric Power Group, LLC v. Alstom S.A.*, 830 F.3d 1350 (Fed. Cir. 2016), for instance, the Court held the claims as drafted

in that case to be patent-ineligible, even though the claim required displaying information in a particular format, i.e., "'displaying concurrent visualization' of two or more types of information," possibly in a "time-synchronized" manner. *Id.* at 1355.

As to the limitations regarding "providing access to . . . data in a clinical environment," we note that they merely "limit[] [the] abstract idea to one field of use" – i.e., "in a clinical environment" – and thus also do not serve to integrate the idea into a practical application. *Bancorp Servs., L.L.C. v. Sun Life Assurance Co. of Canada (U.S.)*, 687 F.3d 1266, 1275–1276, 1280 (Fed. Cir. 2012) (citing *Bilski* for the proposition that "'limiting an abstract idea to one field of use or adding token post-solution components d[oes] not make the concept patentable'" and holding that limiting claims to "use in the life insurance market" does not render them patent-eligible) (alteration in original).

Finally, the limitation of "a processor" merely implements on a computer the abstract mental processes of "aligning . . . sequence data," "detecting . . . signature data," and "removing . . . data other than the signature data." As explained in the Revised Guidance, a judicial exception has not been integrated into a practical application if the additional elements of the claim "merely include[] instructions to implement an abstract idea on a computer, or merely uses a computer as a tool to perform an abstract idea." Revised Guidance, 84 Fed. Reg. at 55.

Mayo Step Two: Whether Claim 1 Amounts to "Significantly More"

Finally, the Revised Guidance directs us to consider whether claim 1 includes "additional elements . . . [that] provide[] 'significantly more' than the recited judicial exception." 84 Fed. Reg. at 56. The Revised Guidance

states that an additional element that "simply appends well-understood, routine, conventional activities previously known in the industry, specified at a high level of generality, to the judicial exception, . . . is indicative that an inventive concept may not be present." *Id*.

Here, as discussed, the only elements recited in claim 1, other than the abstract idea itself, are (1) "obtaining the subject's genomic sequence data using a next generation sequencing apparatus, the genomic sequence data comprising coverage of at least 90% and including signature data . . . "; (2) a processor; (3) "storing the reduced complexity genomic sequence data in a storage structure comprising annotated database entries in a differential DNA storage format, wherein the storage structure encodes acquisition time information . . . and allows for locally unrestrained access to . . . data"; and (4) "providing access to the . . . data in a clinical environment . . . ."

The evidence of record makes clear that all of these additional elements are well-understood, routine, and conventional. With respect to limitations regarding obtaining the subject's genomic sequence data using a next generation sequencing apparatus, the Specification states that "[t]he present invention . . . focuses on the implementation of the sequence information available, prepared, and obtained according to *suitable contemporary sequencing techniques*." Spec. 9:16–18 (emphasis added); *see also* Spec. 7:33–8:2 (stating that "[m]ethods for sequence determination are known to the person skilled in the art" and that "[p]referred are next generation sequencing methods or high throughput sequencing methods"), 1:23–27 (explaining that "next generation sequencing techniques" has dramatically reduced the costs and time needed for obtaining sequence information and that whole genome sequencing is becoming a cost effective

alternative to existing biochemical and genetic tests and assays"), Final Act. 6 (citing references discussing next generation sequencing, including data showing "next generation sequencing can routinely achieve coverage of greater than 90%).

The recitation of a generic "processor" also does not transform the recited patent-ineligible abstract idea into a patent-eligible invention. *Alice*, 573 U.S. at 223. In particular, the claim recites that the processor is configured to "align[] the subject's genomic sequence data with a reference sequence comprising signature data," "detect[] the subject's genomic sequence data comprising signature data," and "remov[e] from the subject's genomic sequence data, data other than the signature data." These steps require the processor to do no more than perform the generic functions of comparing data and deleting data. *See also* Spec. 15:29–31 (stating that "alignment algorithms as known to the person skilled in the art may be employed in order to detect differences between the two genomic sequences), 25:1–3 (stating that "[t]he alignment between the signature reference sequence and the genome sequence obtained from a subject may be carried out according to any suitable alignment method or technique").

The storage structure recited in claim 1 is likewise generic and/or well-known, routine, and conventional. Although claim 1 recites that the storage structure comprises "annotated database entries in a *differential DNA storage structure format*," this phrase does not appear to denote any characteristics that distinguishes the storage structure from a generic database, other than by the content of the information (*e.g.*, inclusion of acquisition time information) that is stored. The Specification, for instance, states that "electronic picture/data archiving and communication system"

currently on the market, such as Philips' iSite PACS systems, may be used as the clinical decision support and storage system of the present invention and may be "adjusted or modified in order to comply with the requirements of the methods of the present invention and/or in order to be able to carry out a computer program or algorithm as described herein, and/or in order to store genomic sequence information and/or functional genetic information as defined herein." Spec. 32:26–33.

As to the limitation regarding "providing access to . . . data in a clinical environment," we have noted above that merely limiting a recited abstract idea to a field of use – i.e., "a clinical environment" – does not render the abstract idea patent-eligible. *Bancorp Servs.*, 687 F.3d at 1275–1276, 1280 (Fed. Cir. 2012). In addition, the potential use of genomic data in a clinical environment is well-known, routine, and conventional. *See, e.g.,* Gatawood ¶ 5 ("Current social, medical, and scientific thinking converges on the idea of 'personalized medicine', broadly interpreted as tailoring clinical decision making based on a patient's genetics.").

Finally, considered as an ordered combination and in the context of the claim as a whole, the additional limitations of claim 1 add nothing that is not already present when the elements are separately considered. Accordingly, we affirm the Examiner's rejection of claim 1 as being directed to an abstract idea without significantly more. Claims 2–4, 6, 8, 9, and 11–18, which are not separately argued, fall with claim 1.

Appellant's Arguments

Appellant first contends that "[t]he 'character as a whole' of the claims is not directed to an abstract idea." Appeal Br. 19; *see also id.* at 24.

As an initial matter, Appellant contends that "the Patent Office has not performed several of the procedural steps required under . . . the 2019 Eligibility Guidance." Appeal Br. 23. Appellant asserts that, "[f]or example, the Patent Office appears to assert that several steps equate to information," but "'information' does not fall within any of the subject matter groupings of abstract ideas enumerated in the 2019 Eligibility Guidance." *Id.* at 24.

We are not persuaded. The Final Rejection was mailed on December 11, 2018, prior to the issuance of the Revised Guidance. The Examiner provided the analysis described in the Revised Guidance in the Answer, including explaining that the claim recites mental processes, which is one of the subject matter groups of abstract ideas enumerated in the Revised Guidance. Appellant has not submitted a Reply Brief disputing the Examiner's analysis.

Appellant contends that the steps recited in the claims "cannot be accomplished by the human mind alone," because

> [t]he claimed invention requires alignment of a reference genome and the genomic sequence data in order to detect signature data in the genomic sequence data, and then requires generation of reduced complexity genomic sequence data by removing certain data from the genomic sequence data. Comparing millions or billions of base pairs, and processing the results of that comparison (including identifying specific signature data and creating new genomes with that signature data removed) is more than a human mind could perform in a lifetime or multiple lifetimes.

Appeal Br. 25.

We are not persuaded. As the Examiner points out, although the claim requires *obtaining* a subject's genomic sequence data comprising

"coverage of at least 90%," under the broadest reasonable interpretation the claim does not limit the size of the subject's genomic sequence data or the reference sequence that must be *aligned*. Ans. 3–4; *see also In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation*, 774 F.3d 755, 763–764 (holding that merely "comparing BRCA [gene] sequences and determining the existence of alternations" is a patent-ineligible mental process).

Appellant next contends that "the claims are directed to a specific improvement in: (1) improved storage efficiency for a database; and (2) retrieval of relevant portions of a subject's whole genome sequence, which facilitates the clinical decision-making pertaining to the subject." Appeal Br. 19. More particularly, Appellant contends that "the claims are directed to reducing the complexity of genomic sequencing data, and storing that data in a specialized storage structure and format that enables unrestrained access to the reduced complexity genomic data and associated time information and other medical data in a clinical environment to facilitate clinical decision-making pertaining to the subject." *Id.* at 24; *see also id.* at 25, 26. Appellant contends that "[t]his processing and specialized storage structure and format is an important application that provides the value of the claimed method": Appellant contends that "the outcome of the method provides clinicians with actionable information that improves patient treatment and care," for example because the data generated by the processing steps "is far more accessible and is immediately available in a clinical environment to facilitate clinical decision-making" as compared to previous data. *Id.* at 24–25, 26.

We are not persuaded. The improvement Appellant refers to is not an improvement in computer *technology* or another *technical* field. Instead, the

alleged improvement in data storage and retrieval results from the abstract idea of deleting non-signature data (i.e., "reducing the complexity of genomic sequencing data") prior to data storage (*e.g.*, because less data is being stored), and the association of the remaining reduced complexity data with additional information such as acquisition time. Even assuming such an abstract idea constitutes a significant improvement in genomic data analysis and storage, an abstract idea that is "[g]roundbreaking, innovative, or even brilliant . . . does not by itself satisfy the § 101 inquiry." *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 591 (2013).

Appellant contends that the claimed invention in fact improves computer technology, in that "[t]he claimed method . . . recites specific steps that . . . allow[] a database to store significantly more genetic data for significantly more people in a manner that enables faster retrieval and analysis of the genetic data." *Id.* at 21–22; *see also id.* at 24, 25. Appellant contends that "[t]his result is not something that current computer systems can accomplish." *Id.* at 22; *see also id.* at 26. Appellant contends that "[a] computer system implementing the claimed method/system is no longer a generic computer, it is a modified computer with improved functionality (both in storage and analytics)," and further argues that "[t]hese improvements transform the claims into patent-eligible subject matter." *Id.* at 27.

We are not persuaded for reasons already discussed above. Appellant does not suggest that the claim allows the database to store more data in the absolute sense – *e.g.*, that the same database would be capable of storing more bits of data. Rather, Appellant appears to argue that the claimed method allows a database to store more "relevant" data and retrieve such

data more rapidly by not storing data deemed to be irrelevant (i.e., data other than the signature data). Such increased storage and faster retrieval times, however, does not change how the *computer* functions; it merely changes the amount and content of genetic data stored and/or processed for each subject. Neither do we agree that a computer system implementing the claimed method/system is thereby transformed into patent-eligible subject matter. Courts have made clear that "merely claiming a software implementation of a purely mental process that could otherwise be performed without the use of a computer" does not render an otherwise ineligible claim patent eligible. *Cybersource*, 654 F.3d at 1375.

Citing *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016) and *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299 (Fed. Cir. 2016), Appellant contends that the fact "the invention comprises a unique data structure in memory, rather than a physical component, does not negate the non-abstract nature of the data structure." Appeal Br. 27; *see also id.* at 20. Appellant argues that, as in *Enfish*, the claimed "novel data structure makes a non-abstract improvement to the computer technology in this system, by formatting the information into a format and data structure that enables faster and more efficient storage and retrieval." *Id.* at 27–28.

Appellant's citation to *Enfish* and *McRO* are inapposite. The claims at issue in *Enfish* are directed to "an innovative logical model for a computer database." 822 F.3d at 1330. As the *Enfish* court explains, "[a] logical model is a model of data for a computer database explaining how the various elements of information are related to one another," and "generally results in the creation of particular tables of data." *Id.* In contrast to the conventional "relational" databases, where "each entity (i.e., each type of thing) that is

modeled is provided in a separate table," the "self-referential" database recited in the *Enfish* claims "includes all data entitles in a single table, with column definitions provided by rows in that same table." *Id.* The patent at issue in *Enfish* teaches that the "self-referential" databases "allow[] for faster searing of data than would be possible with the relational model," "more effective storage of data other than structured text," and "more flexibility in configuring the database." *Id.* at 1333.

In other words, "the self-referential table recited in the claims on appeal is a specific type of data structure designed to improve the way a computer stores and retrieves data in memory." *Id.* at 1339. In contrast, the claims on appeal do not improve the *manner* in which a computer stores and retrieves data in memory; rather, they are directed to determining the *content* of the information to be stored in the database.

Similarly, the claims on appeal are not analogous to the claims at issue in *McRO*, which "uses a combined order of specific rules that renders information into a specific format that is then used and applied to create desired results: a sequence of synchronized, animated characters." 837 F.3d at 1315. As the court explained in its decision, and in contrast to the claims on appeal, the claims do not "simply use a computer as a tool to automate conventional activity" and also "goes beyond merely 'organizing [existing] information into a new form.'" *Id.* at 1314–1315 (alteration original).

Appellant also references *Thales*,[12] *Visual Memory*,[13] *Finjan*,[14] and *Core Wireless*[15] as supporting the proposition that "a claim reciting a software-related invention focused on improving computer technology is not directed to an abstract idea." Appeal Br. 21. These cases are also inapposite for the reason already discussed, namely that claim 1 is not focused on improving computer technology and instead uses the computer only to implement the recited abstract idea.

Finally, with respect to Step 2B of the *Alice*/*Mayo* analysis, Appellant contends that the Examiner fails to show that "the physical data structure recited in the claims, which stores the reduced complexity genomic sequence data comprising annotated database entries in a differential DNA storage structure format, was well-understood, routine, and conventional." Appeal Br. 28.

We are not persuaded. Although the claim recites "a differential DNA storage structure format," the Specification does not define this term, and Appellant has not provided a construction for the term or suggested that the term has a plain and ordinary meaning to a skilled artisan. In addition, there is no evidence that the term refers to a specific logical model for databases, as in *Enfish*; instead, the term at most appears to refer to the content of the information (*e.g.*, the differences between DNA sequences, acquisition time information) to be stored. Under the broadest reasonable interpretation of

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[12] *Thales Visionix Inc. v. United States*, 850 F.3d 1343 (Fed. Cir. 2017).
[13] *Visual Memory LLC v. NVIDIA Corp.*, 867 F.3d 1253 (Fed Cir. 2017).
[14] *Finjan, Inc. v. Blue Coat Sys., Inc.*, 879 F.3d 1299 (Fed. Cir. 2018).
[15] *Core Wireless Licensing S.A.R.L. v. LG Electronics, Inc.*, 880 F.3d 1356 (Fed. Cir. 2018).

the claim, therefore, claim 1 requires that the reduced complexity genomic sequence data be stored as annotated entries in a database that also stores associated acquisition time information and other medical data. As discussed above, such a requirement merely calls for a generic computer component (i.e., a database) performing its conventional function (storing and associating information). *See also* Spec. 32:26–33 (stating that the invention may be implemented in an "electronic picture/data archiving and communication system" currently on the market).

Accordingly, we affirm the Examiner's rejection of claim 1 under 35 U.S.C. § 101 as directed to an abstract idea without significantly more. Claims 2–4, 6, 8, 9, and 11–18, which are not separately argued, fall with claim 1.

B. Obviousness rejections under § 103(a)

1. Issue

The same issue is dispositive as to all of the obviousness rejections; we therefore discuss them together.

The Examiner finds that Chang teaches a "computer-mediated process of comparing a query sequence to a single nucleotide polymorphism (SNP) database," which meets a number of the limitations of claim 1. Final Act. 11–12. However, the Examiner finds that Chang does not explicitly show "sequencing a genome using next-generation sequencing to a coverage of at least 90%," a database "compris[ing] a reference sequence with annotations," "deletion of a portion of the genomic sequence that is not related to sequences pertaining to a disease, . . . linking the sequence data to an individual's medical data, or storing time information." *Id.* at 12.

Nevertheless, the Examiner finds that the other cited references teach these limitations. In particular, the Examiner finds Metzker teaches that "next generation sequencing [technologies] can routinely achieve coverage of greater than 90%" of genomic sequence data. Final Act. 13.

The Examiner also finds that Sherry describes the dbSNP database used by Chang and shows that the "SNPs are shown in association studies showing functional and pharmacogenomics," that date of submission (i.e., time information) is included with the SNP data provided with each submission to the database, and that "entries in dbSNP are annotated." Final Act. 12.

The Examiner further finds that Gatawood teaches the "advantage in storing compressed DNA sequences to conserve computer storage space and facilitate transmission and analysis of DNA sequence data," and also teaches "delta compression" wherein "only the differences relative to a reference sequence" is stored. Final Act. 12.

Finally, the Examiner finds that Kane teaches a "database that combines patient's electronic health record (EHR) . . . , a patient's genotypic record . . . , and a genotype database," wherein data is obtained and/or stored regarding "health risks associated with each genotype," including associations with oncogenesis and associations between SNPs and adverse drug reactions. Final Act. 13. The Examiner finds that Kane also teaches a database including time information (i.e., "the most recent update date for data relevant to a patient's genotype"). *Id.* at 13. The Examiner further finds that Kane teaches paring down patient genotypic data to SNPs that are in a database of risk linkages, and eliminating DNA sequences that does not constitute SNP data. Final Act. 13.

The Examiner concludes that

> [i]t would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the process of Chang . . . by pruning genotype information because Gatawood . . . shows that retaining only differences in sequences relative to a reference sequence allows for reduction in the amount of data needed to characterize variations in genomic samples. It would have been further obvious to link data to an individual's medical record for clinical use because Chang . . . and Sherry . . . show that SNPs can be related to disease[,] and Kane . . . shows pruning of genotype information to retain SNP data relevant to risk of disease or adverse drug reactions and . . . that analysis of individual patients can be performed by including patient genotype data and patient medical record information. It would have been further obvious to include acquisition time information in SNP data because Sherry . . . shows searching SNP data with limiters on time of submission. It would have been further obvious to sequence a genome using next generation sequencing to a coverage of at least 90% because Metzker shows that next generation sequencing has advantages in low cost and allows for high coverage of a genome that is greater than 90%.

Final Act. 14.

Appellant contends that the Examiner has not identified a prior art teaching wherein "a portion of the genomic sequence that is not related to sequences pertaining to one or more specific disorders, diseases, predispositions for a disorder or a disease, or risk factors for development of a disease or disorder is deleted from the obtained genome sequence." Appeal Br. 29.

Appellant does not separately argue the claims. We, therefore, focus our analysis on claim 1 as representative. The issue with respect to these rejections is whether a preponderance of evidence of record supports the

Examiner's conclusion that the cited combination of prior art suggests the limitation of "removing, from [a] subject's genomic sequence data, data other than the signature data to generate reduced complexity genomic sequence data."

2. Analysis

Unless otherwise noted, we adopt the Examiner's findings of fact and reasoning regarding the Examiner's rejection of claim 1 (Final Act. 10–14; Ans. 12) and agree that a preponderance of the evidence of record supports the Examiner's conclusion that claim 1 is obvious in light of the cited prior art. We address Appellant's arguments below.

Appellant contends that neither Gatawood nor Kane discloses deleting "a portion of the genomic sequence that is not related to sequences pertaining to one or more specific disorders, diseases, predispositions for a disorder or a disease, or risk factors for development of a disease or disorder . . . from the obtained genome sequence." Appeal Br. 29. Thus, the corresponding claim limitation at issue is "removing, from the subject's genomic sequence data, data other than the signature data to generate reduced complexity genomic sequence data." *Id.* at 35 (Claim App.)

In particular, Appellant concedes that "Gatawood . . . discloses delta compression to store 'differences relative to a reference sequence.'" Appeal Br. 25. However, Appellant contends that this differs from the claimed invention because,

> if the claimed invention stored "differences relative to a reference sequence," it would include the ***millions*** of bases at which any sequence will differ from a reference sequence, most of which [will have] no relationship to any "genetic or genomic variations specific to one or more disorders, diseases, predispositions for a disorder or

> a disease, or risk factors for development of a disease or disorder." Furthermore, storing only "differences relative to a reference sequence" will necessarily omit the signature data also found in the reference sequence. Accordingly, retaining only differences in sequences relative to a reference sequence is not a suitable method for reducing complexity, and is not the method utilized by the present invention.

Id. at 30.

We are not persuaded by Appellant's argument. The Specification defines "signature data" as follows:

> The term "signature data" as used herein refers to information on a genetic or genomic variation. Preferably, such a signature data may be information on a genetic or genomic variation specific to a disorder, disease, predisposition for disorders or diseases, risk factors for the development of diseases etc. Alternatively, signature data may also comprise data which is not per se linked to a disease or disorder, but provide information on a subject's fitness, robustness, adaptation to specific conditions, potential of adaptability, history of modifications, or information necessary for the subject's or the subject's progeny's identification, e.g. in criminal investigations, fingerprinting approaches, paternity tests etc.

Spec. 20:25–32. Thus, we agree with the Examiner that "differences relative to a reference sequence" is "signature data" within the broadest interpretation of that term, and delta compression to store such differences, which Appellant admits is taught by Gatawood, meets the limitation of "removing . . . data other than the signature data to generate reduced complexity genomic sequence data." Ans. 12.

In this regard, we note that while the claim requires *obtaining* signature data *comprising* genetic or genomic variations specific to diseases,

disorders, or predispositions or risk factors therefor, the claim recites *removing* data other than signature data (i.e., information on a genetic or genomic variation), not data other than the subset of signature data consisting of "genetic or genomic variations specific to" diseases, disorders, or predispositions or risk factors therefor. We further note that while the Specification states that the step of reducing the complexity of genomic data is "preferably carried out on all parts of the genomic sequence except for signature data pertaining to a disease or disorder," *see, e.g.,* Spec. 3:11–15, the Federal Circuit has counseled that "the PTO should avoid . . . limit[ing] broad claim terms solely on the basis of specification passages" and that, "[a]bsent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification or prosecution history when those sources expressly disclaim the broader definition." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004).

Likewise, we are not persuaded by Appellant's argument that Gatawood differs from the claimed invention because Gatawood's method would "necessarily omit the signature data also found in the reference sequence." Appeal Br. 30. The claim requires storage of "reduced complexity genomic sequence data," which is obtained by "removing, *from the subject's genomic sequence data*, data other than the signature data." Appeal Br. 35 (Claims App.) (emphasis added). Thus, under the broadest reasonable interpretation, claim 1 does not require storage of "signature data also found in the reference sequence."

Appellant similarly contends that Kane does not suggest the limitation at issue because

> Kane teaches retention and storage of information about *every* SNP that is maintained in a "[SNP] database of risk linkages" rather than the retention and storage of a plurality of genetic or genomic variations specific to one or more disorders, diseases, predispositions for a disorder or a disease, or risk factors for development of a disease or disorder. Furthermore, in contrast to Kane, the claimed method comprises more than just SNP data, and thus a database comprising only SNPs with some risk linkage would not enable capture of the claimed signature data.

Appeal Br. 31.

We are not persuaded. As an initial matter and as discussed above, the claim does not require retention and storage only of signature data consisting of genetic or genomic variations "specific to one or more disorders, diseases," or predispositions or risk factors therefor. Furthermore, Appellant concedes that Kane teaches retention and storage of information about SNPs maintained in a SNP database of *risk linkages*. Kane explains this database "comprises a collection of established SNP-risk linkages and detailed information about each risk" that allows determination of "a link between the genetic information and the adverse drug reaction information for a single or plurality of patients." Kane ¶ 13. Appellant does not explain why SNPs linked to risks of adverse drug reactions would not fall within the scope of "genetic or genomic variations specific to one or more disorders, diseases," or predispositions or risk factors therefor under the broadest interpretation of the claim.

Finally, we are not persuaded by Appellant's argument that Kane does not suggest the claimed method because "the claimed comprises more than just SNP data, and thus a database comprising only SNPs with some risk linkage would not enable capture of the claimed signature data." As

discussed above, the Specification defines "signature data" as "information on *a* genetic or genomic variation." Spec. 20:25–26 (emphasis added). Claim 1 recites "removing, from the subject's genomic sequence data, data other than the signature data," and further recites

> wherein the signature data comprises *two or more* of a missense mutation, nonsense mutation, single nucleotide polymorphism (SNP), copy number variation (CNV), splicing variation, variation of a regulatory sequence, small deletion, small insertion, small indel, gross deletion, gross insertion, complex genetic rearrangement, inter chromosomal rearrangement, intra chromosomal rearrangement, loss of heterozygosity, and insertion of repeats and deletion of repeats.

Appeal Br. 35 (Claims App.) (emphasis added).

Under the broadest reasonable interpretation, therefore, claim 1 does not require that all possible signature data (i.e., all possible information on a genetic or genomic variation) in the subject's genomic sequence data be stored. In this case, Kane teaches retention and storage of information about SNPs maintained in a SNP database of risk linkages and thus teaches or suggests retaining/storing two or more of SNPs as recited by claim 1.

Accordingly, we affirm the Examiner's rejection of claim 1 as obvious over Chang, Gatawood, Sherry, Metzker, and Kane. Claims 8, 14, and 15, which are not separately argued, fall with claim 1. Appellant does not make any additional arguments with respect to the rejections of claims 2, 13, and 16–18 as obvious over Chang, Gatawood, Sherry, Metzker, Kane, and Greenman; claims 3, 4, and 12 as obvious over Chang, Gatawood, Sherry, Metzker, Kane, and Bollet; claim 6 as obvious over Chang, Gatawood, Sherry, Metzker, Kane, and Langmead; claim 9 as obvious over Chang, Gatawood, Sherry, Metzker, Kane, and Rhodes; and claim 11 as

obvious over Chang, Gatawood, Sherry, Metzker, Kane, and Hwang. Accordingly, we affirm these rejections based on the same reasoning discussed above.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–4, 6, 8, 9, 11–18	101	Eligibility	1–4, 6, 8, 9, 11–18	
1, 8, 14, 15	103(a)	Chang, Gatawood, Sherry, Metzker, Kane	1, 8, 14, 15	
2, 13, 16–18	103(a)	Chang, Gatawood, Sherry, Metzker, Kane, Greenman	2, 13, 16–18	
3, 4, 12	103(a)	Chang, Gatawood, Sherry, Metzker, Kane, Bollet	3, 4, 12	
6	103(a)	Chang, Gatawood, Sherry, Metzker, Kane, Langmead	6	
9	103(a)	Chang, Gatawood, Sherry, Metzker, Kane, Rhodes	9	
11	103(a)	Chang, Gatawood, Sherry, Metzker, Kane, Hwang	11	
Overall Outcome			**1–4, 6, 8, 9, 11–18**	

TIME PERIOD FOR RESPONSE

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

AFFIRMED