UNITED STATES PATENT AND TRADEMARK OFFICE

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Casimir Jones, S.C.
2275 Deming Way, Suite 310
Madison, WI 53562

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pto.correspondence@casimirjones.com

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Ex parte DAVID J. ECKER, STEVEN A. HOFSTADLER,
THOMAS A. HALL, and KRISTIN SANNES-LOWERY

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Appeal 2018-000304
Application 14/047,414[1]
Technology Center 1600

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Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and
TAWEN CHANG, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This Appeal under 35 U.S.C. § 134(a) involves claims 1 and 37–67
(Final Act.[2] 2). Examiner entered a rejection under 35 U.S.C. § 101. We
have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] Appellants identify "Ibis Biosciences" as the real party in interest
(Appellants' May 9, 2017 Appeal Brief (App. Br.) 3).
[2] Examiner's December 9, 2016 Final Office Action.

STATEMENT OF THE CASE

Appellants' disclosure relates "to the field of nucleic acid analysis and provides methods . . . for this purpose when combined with mass spectrometry" (Spec.[3] ¶ 3).

Appellants' claim 1 is representative and reproduced below:

1. A method for analyzing a nucleic acid comprising the steps of:

(a) obtaining a sample comprising nucleic acid for base composition analysis;

(b) amplifying at least two overlapping nucleic acid sequences of a region of said nucleic acid designated as a target for base composition analysis to generate at least two amplification products;

(c) employing a processor for determination of base compositions of said at least two amplification products wherein said processor comprises software that directs said processor to calculate base compositions of said at least two amplification products wherein said base compositions identify the number but not the nucleic acid gene sequence order of A residues, C residues, T residues, G residues and analogs thereof in said amplification products;

(d) employing a processor for comparison of one or more of said base compositions to reference base composition data for said nucleic acid sequence, wherein said reference base composition data comprises at least one database of base compositions of overlapping amplification products on a non-transitory computer readable medium wherein said base compositions identify the number but not the nucleic acid gene sequence order of A residues, C residues, T residues, G residues and analogs thereof in a plurality of said overlapping amplification products wherein said processor comprises software that directs said processor to compare said base

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[3] Appellants' October 7, 2013 Specification.

compositions of said at least two amplification products with said reference base composition data; and

(e) identifying the presence of a particular nucleic acid sequence or variant thereof wherein a match between said base compositions of said at least two amplification products and said reference base composition data identifies the presence of a particular nucleic acid sequence or variant thereof.

(App. Br. 30.)

Claims 1 and 37–67 stand rejected under 35 U.S.C. § 101.

ISSUE

Does the preponderance of evidence of record support Examiner's finding that Appellants' claimed invention is directed to patent ineligible subject matter?

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. *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 thus 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 concepts integrated into 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 182 n.7 (quoting *Corning v. Burden*, 56 U.S. 252, 267–68 (1853))); and manufacturing flour (*Gottschalk*, 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 *Gottschalk* and *Parker*); *see, e.g., id.* at 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 PTO recently published revised guidance on the application of § 101. USPTO, *2019 Revised Patent Subject Matter Eligibility Guidance*, 84 Fed. Reg. 50 (January 7, 2019) ("Revised Guidance"). Under that guidance, 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); and

> (2) additional elements that integrate the judicial exception into a practical application (*see* MPEP § 2106.05(a)–(c), (e)–(h)).

See 84 Fed. Reg. 54–55. 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:

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

(4) 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.

ANALYSIS

Applying the Revised Guidance to the facts on this record, we find that
Appellants' claims are directed to patent-ineligible subject matter. 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: (1) mathematical concepts, (2) certain methods
of organizing human behavior such as fundamental economic practices, and (3)
mental processes.

Examiner finds that Appellants' claims are drawn to a methods of
analyzing nucleic acid using "a computer, computer program or software
and mathematical calculations/algorithms to obtain sequence information"
(Ans.[4] 5; *see also id.* at 4). More specifically, the method of Appellants'
claim 1 comprises the steps of:

(c) employing a processor for determination of base
compositions of said at least two amplification products
wherein said processor comprises software that directs said
processor to calculate base compositions of said at least two
amplification products wherein said base compositions identify
the number but not the nucleic acid gene sequence order of A

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[4] Examiner's August 10, 2017 Answer.

> residues, C residues, T residues, G residues and analogs thereof
> in said amplification products.

(*see* App. Br. 30.) We note, however, that limiting an abstract idea to a particular technological environment, such as a computer, does not confer patent eligibility. *Alice*, 573 U.S. at 222. *See also Intellectual Ventures I LLC v. Capital One Fin. Corp.*, 850 F.3d 1332, 1340 (Fed. Cir. 2017) (Collecting data, without more, is an abstract idea); *Elec. Power Grp. LLC v. Alstom S.A.*, 830 F.3d 1350, 1353–54 (Fed. Cir. 2016) ("[A]nalyzing information by steps people go through in their minds, or by mathematical algorithms, without more, [are] essentially mental processes within the abstract-idea category").

> (d) employing a processor for comparison of one or more of
> said base compositions to reference base composition data for
> said nucleic acid sequence, wherein said reference base
> composition data comprises at least one database of base
> compositions of overlapping amplification products on a non-
> transitory computer readable medium wherein said base
> compositions identify the number but not the nucleic acid gene
> sequence order of A residues, C residues, T residues, G residues
> and analogs thereof in a plurality of said overlapping
> amplification products wherein said processor comprises
> software that directs said processor to compare said base
> compositions of said at least two amplification products with
> said reference base composition data.

(*see* App. Br. 30.) Manipulating data, without more, is a mental process. *Intellectual Ventures I*, 850 F.3d at 1340; *see also Digitech Image Techs., LLC. v. Elecs. For Imaging, Inc.*, 758 F.3d 1344, 1351 (Fed. Cir. 2014) ("Without additional limitations, a process that employs mathematical algorithms to manipulate existing information to generate additional information is not patent eligible"); *Elec. Power Grp. LLC v. Alstom S.A.*, 830 F.3d 1350, 1353–54 (Fed. Cir. 2016) ("[A]nalyzing information by steps

people go through in their minds, or by mathematical algorithms, without more, [are] essentially mental processes within the abstract-idea category").

For the reasons discussed above, the method of Appellants' claim 1 recites a mental process, which is an abstract idea (*see* Final Act. 4 (Examiner finds that Appellants' claims are "directed to an abstract idea which is a judicial exception")).

Having determined that Appellants' claim 1 is directed to a judicial exception, the Revised Guidance directs us to next consider whether the claims integrate the judicial exception into a practical application, the second step of the analysis. On this record, Appellants' claim 1 comprises the step of:

> (a) obtaining a sample comprising nucleic acid for base composition analysis;

> (b) amplifying at least two overlapping nucleic acid sequences of a region of said nucleic acid designated as a target for base composition analysis to generate at least two amplification products;

> (c) employing a processor for determination of base compositions of said at least two amplification products wherein said processor comprises software that directs said processor to calculate base compositions of said at least two amplification products wherein said base compositions identify the number but not the nucleic acid gene sequence order of A residues, C residues, T residues, G residues and analogs thereof in said amplification products; and

> (e) identifying the presence of a particular nucleic acid sequence or variant thereof wherein a match between said base compositions of said at least two amplification products and said reference base composition data identifies the presence of a particular nucleic acid sequence or variant thereof.

(App. Br. 30.)

Those of ordinary skill in this art would have recognized that the steps of obtaining a sample, preparing the sample (e.g., amplifying selected nucleic acid targets for base composition analysis), and using a processor to determine base composition of amplification products are simply insignificant extra-solution data collection steps that neither add significantly more than the abstract idea or integrate the abstract idea into a practical application. *See Mayo* 566 U.S. at 79.

Those of ordinary skill in this art would have also recognized that comparing sequences is nothing more than a mental process that can be performed in one's mind or with the assistance of a pen and paper. *See Versata Dev. Grp. v. SAP Am., Inc.*, 793 F.3d 1306, 1335 (Fed. Cir. 2015) ("Courts have examined claims that required the use of a computer and still found that the underlying, patent-ineligible invention could be performed via pen and paper or in a person's mind"); *see also Elec. Power Grp.*, 830 F.3d at 1353–54 (Analyzing information by steps people go through in their minds, or by mathematical algorithms, do not amount to significantly more than the abstract idea because they are insignificant post-solution activities). Therefore, we conclude that the ineligible subject matter in Appellants' claim 1 is not integrated into a practical application.

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. In this regard, we note that Appellants' method comprises the steps of: "(a) obtaining a sample comprising nucleic acid for base composition analysis" and "(b) amplifying at least two overlapping nucleic acid sequences of a region of said nucleic acid designated as a target for base composition analysis to generate at least two amplification products" (App. Br. 30). As Examiner explains, however, Taylor[5] and Sampath[6] make clear this steps are conventional in this art and represent nothing more than insignificant pre-solution activity (*see* Final Act. 6). "Purely 'conventional or obvious' '[pre]-solution activity' is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law." *Mayo* 566 U.S. at 79 (quoting *Flook*, 437 U.S. at 590). Therefore, we conclude that Appellants' claim 1 does not include an inventive concept.

For the foregoing reasons, we are not persuaded by Appellants' contention "that the present claims clearly provide a new and useful 'application' of an idea, and are clearly more than [a] 'mere recitation of a generic computer'" (App. Br. 14; *see also id.* (Appellants contend that their "claims, as a whole are not directed to an abstract idea, but rather a method of generating and analyzing biological materials" and "recite non-routine

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[5] Taylor et al., *The determination of complete human mitochondrial DNA sequences in single cells: implications for the study of somatic mitochondrial DNA point mutations*, 29 NUCLEIC ACIDS RESEARCH 1–8 (2001).
[6] Sampath et al., US 2006/0259249 A1, published Nov. 16, 2006.

subject matter that is much more than an abstract idea")). For the same reasons, we are not persuaded by Appellants' contention that their

> claims expressly provide methods for <u>amplifying</u> and analyzing overlapping sequences of a region of a nucleic acid of use in identifying the presence of the specific nucleic acid. Thus, [Appellants contend, their] . . . claims involve transformation of physical materials (amplifying at least two overlapping nucleic acid sequences to generate at least two amplification products) . . . [and] [a]s such, the claims, as a whole are not directed to an abstract idea, but rather a method of generating and analyzing biological materials.

(App. Br. 14.)

"[S]imply implementing a mathematical principle on a physical machine, namely a computer, [is] not a patentable application of that principle." *Mayo*, 566 U.S. at 84. Therefore, we are not persuaded by Appellants' contention that their claims "are expressly tied to a particular machine i.e., a processor" (App. Br. 15 (emphasis omitted)).

"[T]he prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment' or adding 'insignificant postsolution activity.'" *Bilski*, 561 U.S. at 610–11, quoting *Diehr*, 450 U.S. at 191–92. Therefore, we are not persuaded by Appellants' field of use contentions (*see* App. Br. 15).

Further, a difference exists between patent ineligible claims, as here, that focuses "on asserted advances in uses to which existing computer capabilities could be put" and patent eligible claims that focus "on a specific improvement . . . in how computers could carry out one of their basic functions of storage and retrieval of data." *Electric Power Group*, 830 F.3d at 1354 (discussing *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335–36

(Fed. Cir. 2016); *see also Research Corp. Technologies, Inc. v. Microsoft Corp.*, 627 F.3d 859, 865 (Fed. Cir. 2010) ("[H]igher quality halftone images [were produced] while using less processor power and memory space."). Therefore, Appellants' contentions relating to *Enfish, DDR Holdings, LLC v. Hotels.com L.P.*, 773 F.3d 1245 (Fed. Cir. 2014), *Bascom Global Internet Serv., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341 (Fed. Cir. 2016), and *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299 (Fed. Cir. 2016) are not persuasive (*see* App. Br. 15–17; Reply Br. 2–3).

In contrast to Appellants' claimed invention, "the claims at issue [in *Enfish*] focused not on asserted advances in uses to which existing computer capabilities could be put, but on a specific improvement-a particular database technique-in how computers could carry out one of their basic functions of storage and retrieval of data." *Electric Power Group*, 830 F.3d at 1354. Further, as Appellants recognize, in contrast to Appellants' claimed invention, the invention claimed in *DDR Holdings* overcame "a problem specifically arising in the realm of computer networks" (*see* App. Br. 15). The Court in *DDR Holdings* determined that the invention was "necessarily rooted in computer technology in order to overcome a problem specifically arising in the realm of computer networks" and that the claimed invention did not simply use computers to serve a conventional business purpose. *DDR Holdings*, 773 F.3d at 1257. Similarly, the claims in *Bascom* provided a software solution applicable to solve a problem specific to the software-based environment of the internet. *See Bascom*, 827 F.3d 1343–45, 1350–51. Thus, notwithstanding Appellants' contentions to the contrary, in contrast to the claims in each of *Enfish, DDR Holdings*, and *Bascom*, Appellants' claimed invention relates to the patent ineligible use to which

existing computer capability could be put. Further, unlike the claims on this record, "[t]he claims in *McRO* were not directed to an abstract idea"; to the contrary, "the claimed improvement [was] allowing computers to produce 'accurate and realistic lip synchronization and facial expressions in animated characters' that previously could only be produced by human animators." *FairWarning IP, LLC v. Iatric Systems, Inc.*, 839 F.3d 1089, 1094 (Fed. Cir. 2016) (internal citation omitted).

Lastly, we note that "[w]hile preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015). "Where a patent's claims are deemed only to disclose patent ineligible subject matter under the *Mayo*[/*Alice*] framework, as they are in this case, preemption concerns are fully addressed and made moot." *Id.* Therefore, we are not persuaded by Appellants' contentions regarding preemption (Reply Br. 5).

CONCLUSION

The preponderance of evidence of record supports 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. Claims 37–67 are not separately argued and fall with claim 1.

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).

AFFIRMED