UNITED STATES PATENT AND TRADEMARK OFFICE

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Ex parte NIGEL GREENWOOD[1]

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Appeal 2018-004017
Application 12/530,533
Technology Center 1600

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Before RICHARD M. LEBOVITZ, FRANCISCO C. PRATS, and
RYAN H. FLAX, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134(a) involving
claims to a method of treating and/or diagnosing a condition of a biological
subject, a processor apparatus for performing such a method, and a program
for such a method. Claims 1, 4–16, 18–25, and 27–30 are on appeal as
rejected under 35 U.S.C. § 101. We have jurisdiction under 35 U.S.C.
§ 6(b).

We affirm.

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[1] Appellant identifies the real party in interest as "Neurotech Research Pty,
Limited." Br. 2.

STATEMENT OF THE CASE

Claims 1, 24, and 25 are independent claims; claim 1 is illustrative and is reproduced below:

    1.   A method of at least one of treating and diagnosing a condition within a biological subject, the method comprising:

    a) using a processing system to determine a base model including one or more equations and associated variables and parameters;

    b) using the processing system to calculate at least one model value using the base model, the at least one model value being a value of at least one of a variable and a parameter;

    c) using the processing system to compare at least one measured subject attribute of the biological subject and at least one corresponding model value to determine a difference between the at least one measured subject attribute and the at least one corresponding model value, the different representing an accuracy of the base model; and

    d) using the processing system to modify the base model in accordance with the determined difference, to improve said accuracy of the base model, the base model being modified by modifying at least one of:

        i) at least one equation; and,

        ii) at least one model value;

    e) using the processing system to repeat steps a) to d) to iteratively modify the base model to thereby generate a subject model, the iterative modifying being performed until at least one of:

        i) the difference is below a predetermined threshold;

        ii) the difference asymptotically approaches an acceptable limit; and,

iii) the difference is minimised; and,

f) using the subject model to derive a value for at least one unmeasured biological attribute of the biological subject; and,

g) at least one of treating and diagnosing a condition within the subject at least partially in accordance with the at least one unmeasured biological attribute.

Br. 17–18 (Claims Appendix). Independent claims 24 and 25 recite the same steps; however, claim 24 includes these steps as programming for a processor, which is part of an apparatus, and claim 25 includes the steps as computer code to be executed by a processor.

The following rejection is appealed:

Claims 1, 4–16, 18–25, and 27–30 stand rejected under 35 U.S.C. § 101 as directed to an abstract idea without significantly more so as to provide an inventive concept. Final Action 2.

DISCUSSION

"[T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). We have considered those arguments made by Appellant in the Appeal Brief (no Reply Brief was submitted); arguments not so presented in the Brief are deemed to have been waived. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2015); *see also Ex parte Borden*, 93 USPQ2d 1473, 1474 (BPAI 2010) (informative) ("Any bases for asserting error, whether factual or legal, that are not raised in the principal brief are waived.").

"Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012) (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)). Claims directed to *nothing more* than abstract ideas (such as mathematical algorithms), natural phenomena, and laws of nature are not eligible for patent protection. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); *accord* MPEP § 2106 (II) (discussing *Diehr*).

In analyzing patent-eligibility questions under the judicial exception to 35 U.S.C. § 101, the Supreme Court instructs us to "first determine whether the claims at issue are directed to a patent-ineligible concept." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 218 (2014). If the claims are determined to be directed to an ineligible concept we then move to a second step and "consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* at 217 (quoting *Mayo*, 566 U.S. at 77–78).

In addition to this direction by the Supreme Court, the United States Patent and Trademark Office ("USPTO") published revised guidance on the application of § 101. USPTO's January 7, 2019 Memorandum, *2019 Revised Patent Subject Matter Eligibility Guidance* ("2019 Guidance Memorandum"). Under this guidance, in step one of the *Mayo/Alice* framework, in analyzing the issue of abstract ideas we first look to whether the claim recites:

> (Step 1, Prong 1) any judicial exceptions, including certain groupings of abstract ideas (i.e., mathematical concepts, certain

4

methods of organizing human interactions such as a fundamental economic practice, or mental processes); and

(Step 1, Prong 2) additional elements that integrate the judicial exception into a practical application (*see* MPEP § 2106.05(a)-(c), (e)-(h)).

Furthermore, under the guidance, regarding step two of the *Mayo/Alice* framework, only if a claim is determined to (1) recite a judicial exception and (2) not integrate that exception into a practical application, do we then proceed to (the *Mayo/Alice*) Step 2 and look to whether the claim:

(3) adds a specific limitation beyond the judicial exception that is 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.

As identified above, claims 1, 24, and 25 are substantially similar and, further, Appellant argues the claims as a group, except for stating the Examiner did not sufficiently address claims 24 and 25 individually. Br. 7–16. This argument is not persuasive. The Examiner analyzed claim 1, in depth, and claims 1, 24, and 25 are essentially the same other than the slight differences identified above. The Examiner's analysis of claim 1, therefore, indisputably relates to and covers the other independent claims. *See* Answer 9. Furthermore, Appellant did not separately argue any dependent claim. *Id.* We, therefore, address all claims as a group.

Regarding *Mayo/Alice's* step one, the Examiner determined that:

The claims are directed to a method and process steps of ***determining*** a base model comprising at least one equation, variables and parameters, ***calculating*** at least one model value using the base model, ***comparing*** one measured subject attribute

5

of a biological subject and at least one corresponding model value to determine a difference therebetween, *modifying* the model comprising at least one equation, using the model to derive a value to one unmeasured biological attribute, and diagnosing a condition. The method further includes *processing the data using the Layapunov function which is a mathematical function* and wherein the model is for a biological disorder. As a whole the method relies on the *abstract ideas of performing mathematical calculations and using mathematical relationships and formulas* (see the July 2015 Update: Interim Eligibility Guidance Identifying Abstract Ideas). The recited diagnosis is also *an abstract idea step as it may be performed as a mental step*.

Final Action 2–3 (emphasis added). Regarding the *Mayo/Alice* Step 2, the Examiner determined:

> The claims also recite non-abstract idea, physical limitations, which are the additional elements of treating [or diagnosing] a condition within a subject, an apparatus for performing the computational steps and a computer program product to perform the computational steps.
>
> The claims do not include additional elements that are sufficient to amount of significantly more than the judicial exception because it is routine and conventional to treat a patient using information from calculations and perform computational calculations using a processing system. The claimed elements include the apparatus recited in claim 24 and computer program product of claim 25 are a recitation of *generic computer structure that serve to perform generic computer functions that are well-understood, routine, and conventional activities previously known to the pertinent industry. Viewed as a whole, these additional claim element(s) do not provide meaningful limitation(s) to transform the abstract idea into a patent eligible application of the abstract idea such that the claim(s) amounts to significantly more than the abstract idea itself.* Therefore, the claim(s) are rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter.

Final Action 3–4 (emphasis added). Although we conclude, contrary to the Examiner's rationale, that the claims do not require any form of treatment because it is expressed as an optional, alternative, claim element with respect to diagnosing, we discern no reversible error in the Examiner's determinations and rationale. We analyze the record pursuant to the 2019 Guidance Memorandum and address Appellant's arguments below.

STEP 1, PRONG 1[2]

The 2019 Guidance Memorandum identifies three key concepts identified as abstract ideas:

> (a) mathematical concepts including "mathematical relationships, mathematical formulas or equations, mathematical calculations"; (b) certain methods of organizing human activity, such as "fundamental economic principles or practices," "commercial or legal interactions," and "managing personal behavior or relationships or interactions between people"; and (c) mental processes including "observation, evaluation, judgment, [and] opinion."

Here, the independent claims recite, *inter alia*: (1) "determin[ing] a base model including one or more equations and associated variables and parameters"; (2) "calculat[ing] at least one model value using the base model, the at least one model value being a value of at least one of a variable and a parameter"; (3) "compar[ing] at least one measured subject attribute of the biological subject and at least one corresponding model value to determine a difference"; (4) "modify[ing] the base model in accordance with the determined difference, to improve said accuracy of the base model . . .

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[2] The USPTO 2019 Guidance Memorandum refers to this, along with Prong 2, as "Step 2A."

by modifying at least one of: i) at least one equation; and, ii) at least one model value"; (5) "repeat[ing these] steps . . . to iteratively modify the base model to thereby generate a subject model . . ."; and (6) treating and/or diagnosing a condition "at least partially in accordance with the at least one unmeasured biological attribute." *See supra* claim 1. Limitations (1) through (5) recite mental steps of determining, calculating, comparing, modifying, and repeating, which are observations, evaluations, judgments, and opinions that can be performed in the mind. In addition, each of limitations (1), (2), (3), (4), and (5) recites a mathematical concept, either expressly as "calculating" or using an "equation" or implicitly in the use of mathematical models, values, variables, and parameters, which are mathematical relationships.

As identified in the Specification, the claimed model(s) are "typically in the form of a set of Ordinary Differential Equations (ODEs) or Difference Equations (DEs) that can be used to express basic responses of a subject" where " a mixture of variables and parameters [ ] represent the condition within the subject." Spec. 9:6–9. The Specification further states, "[t]he model could be derived by an operator," i.e., as a mental step using math. *Id.* at 9:18. Moreover, the Specification states, the "person skilled in the art will appreciate that aspects of the above outlined procedure may be performed manually. However, in order to achieve this it will be necessary for an individual to perform significantly complicated mathematics in order to analyse the measured subject attributes and calculate a suitable model." *Id.* at 11:24–27. Thus, the Specification supports the conclusion that the claims recite mental steps and mathematical relationships.

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, "[i]f 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). Therefore, our reviewing court's and the Supreme Court's precedent supports that the claims here recite abstract ideas.

Accordingly, we conclude, in agreement with the Examiner and Appellant's Specification, the claims recite a mental process and mathematical relationships and, thus, an abstract idea.

Appellant agues the Examiner's analysis failed to explain why the claimed subject matter corresponds to any concept that the courts have identified as an abstract idea. Br. 9. As we identify above, the claims are directed to mental steps and mathematical relationships, which our reviewing court, as well as the Supreme Court, have held to be abstract ideas. Thus, this argument is not persuasive.

Appellant argues the Examiner failed to consider all the claimed limitations, for example: the modifying using an equation and model value; and the iterative modifying based on a threshold, and acceptable limit, and minimizing a difference. Br. 10. It is apparent that the Examiner did consider all the claim limitations, including these. *See* Final Action 2–3; Answer 4–5. Likewise, here, we have considered all the claim limitations and agree with the Examiner's determinations. Appellant's argument is not persuasive.

STEP 1, PRONG 2

We next consider whether the claimed method/processing-system/program includes additional elements that integrate the abstract idea into a practical application. Determining that the claimed abstract idea is integrated into a practical application requires identifying an additional element or a combination of additional elements in the claim to 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 exception.

The claim recites a step of "at least one of treating and diagnosing a condition within the subject at least partially in accordance with the at least

one unmeasured biological attribute," which requires only treating or diagnosing (not both), and, in the case of claims 24 and 25, the use of a generic computer to perform the abstract idea. With respect to the "diagnosing" aspect, diagnosis is a mental step because it involves merely making a mental observation that a patient has or does not have a disease. It is therefore insufficient to integrate into a practical application. The analysis could end here because the claim only requires one of diagnosis or treating. However, the "treating" step, which is optional, does not require a specific treatment and therefore is simply a direction to telling the doctor to treat the patient, without a specific application as to how the patient is to be treated.

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 forming models and in mathematical calculations. And, the end result of the claimed method (or the product of the claimed apparatus and computer program) amounts to data (a diagnosis).

Here, it cannot be reasonably argued that the claims do not recite mental steps and mathematical relationships, as determined by the Examiner and as discussed above. Furthermore, it is this series of mental steps and mathematical relationships to which Appellant's invention, as claimed, is directed. There are no limitations requiring that the information derived from choosing a model and doing math result in actual actions being taken or anything other than data be produced. For example, there is no treatment required to be performed based on the mental steps and mathematical relationships. *Cf. Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018) (claims required using a natural relationship to

perform a new treatment and were directed to the treatment and, so, were patent-eligible). The claims here explicitly require only one of treating and diagnosing, so no treatment is required. Thus, there is no integration of the abstract idea into a practical application.

Appellant argues the claims are not directed to an abstract idea, but rather, recite an improvement to computer-related technology, analogizing the invention, which uses "Liapunov functions," *sic*, to the patent-eligible inventions of *Enfish*, *McRO*, and *BASCOM*, and, further, Appellant argues that the claimed invention does not preempt other approaches. Br. 10–16 (citing *Enfish, LLC v. Microsoft Corp.*, 822 F. 3d 1327 (Fed. Cir. 2016); *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299 (Fed. Cir. 2016); *Bascom Global Internet Serv., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341 (Fed. Cir. 2016)). These arguments are not persuasive.

Unlike *Enfish*, where the Federal Circuit found the claims to be patent-eligible as directed to an improvement in how computers function, here, although the claims are directed, essentially, to software or programming (if the method is not wholly performed in the mind); they are not "directed to a specific implementation of a solution to a problem in the software arts," as were the claims in *Enfish*. *See Enfish*, 822 F.3d at 1339. Appellant's invention, while possibly an improvement in how diagnosis is made, does not improve how a computer or other implement functions. *Synopsys*, 839 F.3d at 1151 (a new abstract idea remains an abstract idea).

In *McRO* the Federal Circuit held claims that "set out meaningful requirement for [a] first set of rules" by which a computer could synchronize animated lip movements to spoken sounds, as a whole, were directed to "a

process specifically designed to achieve an improved technological result,"
that result being a computer-generated animation having automatically
synchronized mouth movements, and were not directed to an abstract idea.
McRO, 837 F.3d at 1316. Here, we have none of the claimed specificity of
technological improvement the Federal Circuit found present in the
invention of *McRO*, but only different mathematical concepts for improving
diagnosis, which itself is a mental observation. Also, contrary to *McRO*,
where the ultimate product produced was a synchronized computer
animation, here the result of the claimed method or the output of the claimed
product is the output of a diagnosis, which is data and a mental observation.

Unlike *Bascom*, where the claims provided a software solution
applicable to solve a problem specific to the software-based environment of
the internet, the claims here are directed to new calculations with data. *See*
Bascom, 827 F.3d 1343–45, 1350–51. In *Bascom*, a technological problem
related directly to internet use was identified and specifically solved with the
claimed invention, i.e., having filtering software on each local computer was
disadvantageous, and a would-be solution using remote, but inflexible,
filters was also disadvantageous, so the invention provided remote and
customizable filters for the internet. This is different from the claimed
invention here, which is a new algorithm for fine tuning mathematical
models, or mathematical relationships used to modify other mathematical
relationships relating to biological systems.

As discussed above, the claimed invention (if not actually performed
in the human mind) is software programming; it does not improve the
functioning of a computer; it is not effecting a treatment for a medical

13

condition; it is not transforming a machine or matter in any way. *See, e.g.,*
MPEP § 2106.05(a)–(c). The only "implementations" of the abstract idea,
as claimed, are directed to generic data processing (programming) and
generic devices and the claims' limitations to such amount to mere
instruction to apply the abstract idea.

Moreover, tying the invention's software to improving models or
diagnosis or a computer environment, i.e., a technical field, without more, is
not a practical implementation of the abstract idea. *See, e.g.,* MPEP
§ 2106.05(h); *see also Parker v. Flook,* 437 U.S. 584, 588–90 (1978)
(limiting an abstract idea to one field of use or adding token post-solution
components did not make the concept patentable). Tying a claimed mental
process or mathematical formula to specific data cannot turn an abstract idea
into patent-eligible subject matter because "mere '[data-gathering] step[s]
cannot make an otherwise nonstatutory claim statutory.' *In re Grams,* 888
F.2d 835, 840 (Fed.Cir.1989) (quoting *In re Meyer,* 688 F.2d 789, 794
(CCPA 1982))." *CyberSource,* 654 F.3d at 1370.

Appellant also argues there is an absence of preemption in view of the
claimed invention (*see, e.g.,* Appeal Br. 9); however, it is well-established
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.*
Thus, this argument is also not persuasive.

STEP 2 – INVENTIVE CONCEPT[3]

Regarding *Mayo/Alice's* step two, as noted above, the Examiner determined "[t]he claims do not include additional elements that are sufficient to amount of significantly more than the judicial exception," because using generic computers structures to implement an abstract idea (or outputting data) do not provide meaningful limitations to transform the abstract idea into an inventive concept. Final Action 3–4. Again, we discern no error in the Examiner's determinations.

We are not persuaded that the Examiner erred in determining that the elements of claim 1, considering all elements both individually and as an ordered combination, do not amount to significantly more than the abstract ideas of a mental process and mathematical concepts. Looking at claim 1, for example, we ask what more is claimed once we exclude the limitations directed to the abstract idea and, what we find is, essentially, nothing beyond the idea. The determining, calculating, comparing, modifying, and repeating limitations of claim 1, discussed above, are each and all directed to the abstract idea. Once removed from consideration, we are left with the collection of patient data and the outputting of data. Regarding claims 24 and 25, the additionally claimed subject matter amounts to generic computer components. *See, e.g.*, Spec. 12:3–5.

The Federal Circuit has established that collecting, classifying, storing, and organizing data, regardless of whether such data manipulations are limited to a particular technological environment, is an abstract idea and, assuming it not to be integrated into a practical application, without more

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[3] The USPTO 2019 Guidance Memorandum refers to this as "Step 2B."

(which cannot be provided by generic components or steps used in their routine and customary ways), is not patent eligible. *See, e.g., Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335 (Fed. Cir. 2018) (claims directed to manipulating data for selective display using routine and conventional instructions/programming not patent-eligible); *SAP America, Inc. v. Investpic, LLC*, 890 F.3d 1016, 1018 (Fed. Cir. 2018) (claims directed to "nothing but a series of mathematical calculations based on selected information and the presentation of the results of those calculations" is merely an advancement in an abstract idea and patent-ineligible, even though physical things like databases and processors are claimed); *In re TLI Communications LLC Patent Litigation*, 823 F.3d 607 (Fed. Cir. 2016) (collecting and organizing data in the form of digital images is abstract and patent ineligible, and using computer systems in their generic ways do not add an inventive concept); *Content Extraction and Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n*, 776 F.3d 1343 (Fed. Cir. 2014) (extracting data from documents, recognizing information therefrom, and storing the information is abstract). Furthermore, the mere output of data is an insignificant extra-solution activity and does not confer patent eligibility. *Apple Inc. v. Ameranth, Inc.*, 842 F.3d 1229, 1241–42 (Fed. Cir. 2016) (printing or downloading generated menus is an insignificant application).

Appellant points to nothing in the claims that adds an inventive concept or some additional, non-routine, subject matter so as to confer patent eligibility to an abstract idea. Once we strip away the limitations directed to the abstract idea, we are left with: either treating or diagnosing, which amounts to outputting data and making a mental observation; a generic

processing system having a generic processor; and/or a computer program. Outputting data (a diagnosis) as a result of considering data adds no inventive concept to the claimed invention when considered individually and with the other steps as an ordered combination. Reciting generic computer components, likewise, adds no inventive concept.

For the above reasons, we are unpersuaded that the Examiner erred in determining the claims to be patent-ineligible.

SUMMARY

The rejection of the claims as directed to patent-ineligible subject matter is affirmed.

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)(1)(iv).

AFFIRMED