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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte WILLIAM H. DUMOUCHEL and ROBERT WEBER

Appeal 2019-002136
Application 13/886,719
Technology Center 3600

Before NINA L. MEDLOCK, PHILIP J. HOFFMANN, and BRUCE T. WIEDER, *Administrative Patent Judges*.

MEDLOCK, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant[1] appeals under 35 U.S.C. § 134(a) from the Examiner's final rejection of claims 1, 4, 6, 7, 10, 12, 13, 16, and 18–24.[2] We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

CLAIMED INVENTION

Appellant's claimed invention relates "generally to a computer system, and in particular to a computer system that estimates risk for inspection sites" (Spec. ¶ 1).

Claims 1, 7, and 13 are the independent claims on appeal. Claim 1, reproduced below with bracketed notations added, is illustrative of the claimed subject matter:

> 1. A non-transitory computer readable medium having instructions stored thereon that, when executed by a processor, cause the processor to schedule compliance inspections by a pharmacovigilance team of pharmaceutical product manufacturing sites based on risk scores, the scheduling comprising:

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[1] We use the term "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Our decision references Appellant's Appeal Brief ("Appeal Br.," filed September 4, 2018) and Reply Brief ("Reply Br.," filed January 16, 2019), and the Examiner's Answer ("Ans.," mailed November 16, 2018) and Final Office Action ("Final Act.," mailed February 22, 2018). Appellant identifies Oracle International Corporation as the real party in interest. Appeal Br. 2.

[2] Appellant filed an Amendment After Final on April 20, 2018. That Amendment would have canceled claims 6, 12, and 18. However, the Examiner declined to enter the Amendment. *See* Advisory Action mailed May 16, 2018. The Claim Appendix, included in the Appeal Brief, is incorrect in its identification of claims 6, 12, and 18 as canceled.

[(a)] receiving data relating to a plurality of pharmaceutical product manufacturing sites, each pharmaceutical product manufacturing site having a corresponding management entity, wherein

each compliance inspection is an internal audit conducted by the pharmacovigilance team and comprises, at the pharmaceutical product manufacturing site, at least one of reviewing documents, reviewing quality records, examining facilities, examining assets, conducting tests, or taking measurements, and

the data comprises, for each of the pharmaceutical product manufacturing sites, unobserved risk parameters, a plurality of previous compliance inspection results at the pharmaceutical product manufacturing site including observed inspection data, and observed data for the corresponding management entity;

[(b)] estimating a plurality of hyper-parameters based on the data, the hyper-parameters determining assumed prior probabilistic relationships among the unobserved risk parameters;

[(c)] for each of the pharmaceutical product manufacturing sites, determining a risk score that corresponds to expected deficiencies that would be found if the pharmaceutical product manufacturing site was inspected, wherein a poor risk score corresponds to a higher risk of having deficiencies, and at least one previous deficiency identified by the plurality of previous compliance inspection results at the pharmaceutical product manufacturing site worsens the determined risk score for the pharmaceutical product manufacturing site based, at least in part, upon an amount of time that has elapsed since the previous deficiency was identified; and

[(d)] scheduling the compliance inspections of the pharmaceutical product manufacturing sites by the pharmacovigilance team based on the determined risk score, wherein pharmaceutical product manufacturing sites that have a higher estimated level of risk are scheduled before pharmaceutical product manufacturing sites that have a lower estimated level of risk,

wherein the risk score is based on a statistical model comprising a relationship between the unobserved risk parameters for the pharmaceutical product manufacturing site, the observed inspection data for the pharmaceutical product manufacturing site, and the observed data for the corresponding management entity of the pharmaceutical product manufacturing site, the risk score having a binomial distribution with a mean $\exp(\theta_{isq})$, and

wherein the statistical model includes a logistic regression relationship between observed events and risk parameters that is given by:

$$P(Y_{isqk}=1) = 1/[1 + \exp(a_k - b_k\ \theta_{isq})],$$

where P() indicates a probability function,

where Y_{isqk} indicates a presence or absence of a particular event k at a particular time period q relating to a particular management entity i and pharmaceutical product manufacturing site s,

where θ_{isq} are the unobserved risk parameters for pharmaceutical product manufacturing site i,

where i=1, . . ., C; where C is a total number of management entities,

where s=1, . . ., Si; where Si is a total number of pharmaceutical product manufacturing sites for management entity i,

where q=1, . . ., Q; where Q is a total number of time periods,

where k=1, . . ., K; where K is a total number of events, and

where a_k and b_k are estimated logistic coefficients for event k.

REJECTION[3]

Claims 1, 4, 6, 7, 10, 12, 13, 16, and 18–24 are rejected under 35 U.S.C. § 101 as directed to a judicial exception without significantly more.

ANALYSIS

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

The Supreme Court, in *Alice*, reiterated the two-step framework previously set forth in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), "for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Alice Corp.*, 573 U.S. at 217. The first step in that analysis is to "determine whether the claims at issue are directed to one of those patent-ineligible concepts." *Id.* If the claims are not directed to a patent-ineligible concept, e.g., an abstract idea, the inquiry ends. Otherwise, the inquiry proceeds to the second step where the elements of the claims are considered "individually and 'as an ordered combination'" to determine whether there are additional elements that "'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo*, 566 U.S. at 79, 78). This is "a search for an 'inventive concept' — *i.e.*, an

[3] The Examiner has withdrawn the rejection of claims 1, 4, 6, 7, 10, 12, 13, 16, and 18–24 under 35 U.S.C. § 103. Ans. 3.

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 217–18 (alteration in original).

In rejecting the pending claims under 35 U.S.C. § 101, the Examiner determined that the claims are directed to scheduling compliance inspections of pharmaceutical product manufacturing sites based on a determined risk score that is calculated based on a statistical model, i.e., to a method of organizing human activity and a mathematical relationship/formula, and, therefore, to an abstract idea similar to other concepts that the courts have held abstract (Final Act. 11–18). The Examiner also determined that the claims do not include additional elements or a combination of elements sufficient to amount to significantly more than the abstract idea itself (*id.* at 18–23).

After Appellant's Appeal Brief was filed, and the Examiner's Answer mailed, the U.S. Patent and Trademark Office (the "USPTO") published revised guidance for use by USPTO personnel in evaluating subject matter eligibility under 35 U.S.C. § 101. 2019 REVISED PATENT SUBJECT MATTER ELIGIBILITY GUIDANCE, 84 Fed. Reg. 50, 57 (Jan. 7, 2019) (the "2019 Revised Guidance"). That guidance revised the USPTO's examination procedure with respect to the first step of the *Mayo*/*Alice* framework by (1) "[p]roviding groupings of subject matter that [are] considered an abstract idea"; and (2) clarifying that a claim is not "directed to" a judicial exception if the judicial exception is integrated into a practical application of that exception. *Id.* at 50. The 2019 Revised Guidance, by its terms, applies to all

applications, and to all patents resulting from applications, filed before, on, or after January 7, 2019. *Id.*[4,5]

Independent Claim 1 and Dependent Claims 4, 19, and 21

Step One of the Mayo/Alice Framework (*2019 Revised Guidance, Step 2A*)

The first step in the *Mayo*/*Alice* framework, as mentioned above, is to determine whether the claims at issue are "directed to" a patent-ineligible concept, e.g., an abstract idea. *Alice Corp.*, 573 U.S. at 217. This first step, as set forth in the 2019 Revised Guidance (i.e., Step 2A), is a two-prong test; in Step 2A, Prong One, we look to whether the claim recites a judicial exception, e.g., one of the following three groupings of abstract ideas: (1) mathematical concepts; (2) certain methods of organizing human activity, e.g., fundamental economic principles or practices, commercial or legal interactions; and (3) mental processes. 2019 Revised Guidance, 84 Fed. Reg. at 54. If so, we next consider whether the claim includes additional elements, beyond the judicial exception, that "integrate the [judicial] exception into a practical application," i.e., that apply, rely on, or

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[4] The 2019 Revised Guidance supersedes MANUAL OF PATENT EXAMINING PROCEDURE ("MPEP") § 2106.04(II) and also supersedes all versions of the USPTO's "Eligibility Quick Reference Sheet Identifying Abstract Ideas." *See* 2019 Revised Guidance, 84 Fed. Reg. at 51 ("Eligibility-related guidance issued prior to the Ninth Edition, R-08.2017, of the MPEP (published Jan. 2018) should not be relied upon."). Accordingly, Appellant's arguments challenging the sufficiency of the Examiner's rejection will not be addressed to the extent those arguments are based on currently-superseded USPTO guidance.

[5] The USPTO issued an update on October 17, 2019 (the "October 2019 Update: Subject Matter Eligibility," available at https://www.uspto.gov/sites/default/files/documents/peg_oct_2019_update.pdf) clarifying the 2019 Revised Guidance in response to comments solicited from the public.

use the judicial exception in a manner that imposes a meaningful limit on the judicial exception, such that the claim is more than a drafting effort designed to monopolize the judicial exception ("Step 2A, Prong Two"). *Id.* at 54–55. Only if the claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application do we conclude that the claim is "directed to" the judicial exception, e.g., an abstract idea. *Id.*

We are not persuaded by Appellant's arguments that the Examiner erred in determining that claim 1 is directed to an abstract idea (Appeal Br. 8–17). The Federal Circuit has explained that "the 'directed to' inquiry applies a stage-one filter to claims, considered in light of the specification, based on whether 'their character as a whole is directed to excluded subject matter.'" *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335 (Fed. Cir. 2016) (quoting *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1346 (Fed. Cir. 2015)). It asks whether the focus of the claims is on a specific improvement in relevant technology or on a process that itself qualifies as an "abstract idea" for which computers are invoked merely as a tool. *See id.* at 1335–36. Here, it is clear from the Specification (including the claim language) that the claims focus on an abstract idea, and not on any improvement to technology and/or a technical field.

The Specification is titled "RISK ESTIMATION OF INSPECTION SITES," and states that one embodiment is directed, in particular, to a computer system that estimates risk for inspection sites (Spec. ¶ 1). The Specification describes, in the Background section, that an inspection (also referred to as an audit) is generally understood as an organized examination or evaluation conducted at a site, and may involve the review of documents and quality records, the conducting of various tests, and/or the taking of

various measurements (*id.* ¶ 2). Such an inspection may be conducted, for example, to ensure that a site complies with established regulations and/or standards, to regulate the quality of goods produced or services performed at the site, to ensure that proper manufacturing methods are performed at the site, to ensure that contaminants are properly controlled at the site, to ensure that safe working conditions exist at the site, or to ensure that waste materials are properly disposed of (*id.*). When a site fails to meet the regulations and/or standards that pertain to an inspection, and, thus, fails inspection, the inspection typically describes specific deficiencies, i.e., the "findings" of the inspection, which contributed to the failure (*id.* ¶ 4).

The Specification describes that known inspection systems generally schedule inspections by listing the sites to be inspected, sequentially inspecting each listed site from a first site to a last site, and then conducting subsequent rounds of inspection, again starting with the first site and ending at the last site (*id.* ¶ 11). These previous approaches "generally did not schedule inspections for sites based on any determined risk score that corresponds to expected deficiencies that would result"; instead, the Specification describes that previous approaches scheduled site inspections based on "historic estimates of risk at the time of the previous inspections, as opposed to using any systematic analysis of data" (*id.*). "For example, the previous approaches generally would, at most, estimate the risk that a specific site will fail an inspection based upon an immediately preceding inspection result for the specific site"; a specific site would, therefore, be deemed to have higher risk of failing inspection if the site failed the immediately preceding inspection (*id.*).

In contrast to the previous approaches, the Specification describes that one embodiment of the present invention estimates the risk that a particular site will have deficiencies by determining a risk score (corresponding to the expected deficiencies) based on a systematic data analysis, e.g., by examining: (1) a plurality of previous inspection results of the site, (2) site self-assessment results and other information collected about the site or its company, (3) the amount of time that has elapsed since previous inspections, (4) potential correlations of risk that may exist among other sites that are governed by the same management, and (5) a totality of risk information for companies and sites for the respective industry or regulated area in the inspection program (*id.* ¶ 12). These estimates are then used to give greater priority for future inspections to sites that are determined to be at high risk for poor risk scores (*id.* ¶ 20).

Consistent with this disclosure, claim 1 recites a non-transitory computer readable medium having instructions stored thereon that, when executed by a processor, cause the processor to schedule compliance inspections of pharmaceutical product manufacturing sites based on risk scores, the scheduling comprising: (1) receiving data relating to a plurality of pharmaceutical product manufacturing sites, including, for each of the manufacturing sites, unobserved risk parameters, a plurality of previous compliance inspection results at the site including observed inspection data, and observed data for the site's management entity, i.e.,

> receiving data relating to a plurality of pharmaceutical product manufacturing sites, each pharmaceutical product manufacturing site having a corresponding management entity, wherein
>
> each compliance inspection is an internal audit conducted by the pharmacovigilance team and comprises,

> at the pharmaceutical product manufacturing site, at least one of reviewing documents, reviewing quality records, examining facilities, examining assets, conducting tests, or taking measurements, and
>
> the data comprises, for each of the pharmaceutical product manufacturing sites, unobserved risk parameters, a plurality of previous compliance inspection results at the pharmaceutical product manufacturing site including observed inspection data, and observed data for the corresponding management entity

(step (a)); (2) "estimating a plurality of hyper-parameters based on the data, the hyper-parameters determining assumed prior probabilistic relationships among the unobserved risk parameters" (step (b)); (3) for each of the pharmaceutical product manufacturing sites, determining a risk score that corresponds to expected deficiencies that would be found if the pharmaceutical product manufacturing site was inspected, i.e.,

> for each of the pharmaceutical product manufacturing sites, determining a risk score that corresponds to expected deficiencies that would be found if the pharmaceutical product manufacturing site was inspected, wherein a poor risk score corresponds to a higher risk of having deficiencies, and at least one previous deficiency identified by the plurality of previous compliance inspection results at the pharmaceutical product manufacturing site worsens the determined risk score for the pharmaceutical product manufacturing site based, at least in part, upon an amount of time that has elapsed since the previous deficiency was identified

(step (c)); and (4) scheduling compliance inspections of the pharmaceutical product manufacturing sites based on the determined risk score such that manufacturing sites that have a higher estimated level of risk are scheduled before sites that have a lower estimated level of risk, the risk score being based on a statistical model, including a logistic regression relationship, i.e.,

scheduling the compliance inspections of the pharmaceutical product manufacturing sites by the pharmacovigilance team based on the determined risk score, wherein pharmaceutical product manufacturing sites that have a higher estimated level of risk are scheduled before pharmaceutical product manufacturing sites that have a lower estimated level of risk,

wherein the risk score is based on a statistical model comprising a relationship between the unobserved risk parameters for the pharmaceutical product manufacturing site, the observed inspection data for the pharmaceutical product manufacturing site, and the observed data for the corresponding management entity of the pharmaceutical product manufacturing site, the risk score having a binomial distribution with a mean $\exp(\theta_{isq})$, and

wherein the statistical model includes a logistic regression relationship between observed events and risk parameters that is given by:

$$P(Y_{isqk}=1) = 1 /[1 + \exp(a_k – b_k \theta_{isq})],$$

where P() indicates a probability function,

where Y_{isqk} indicates a presence or absence of a particular event k at a particular time period q relating to a particular management entity i and pharmaceutical product manufacturing site s,

where θ_{isq} are the unobserved risk parameters for pharmaceutical product manufacturing site i,

where i=1, . . ., C; where C is a total number of management entities,

where s=1, . . ., Si; where Si is a total number of pharmaceutical product manufacturing sites for management entity i,

where q=1, . . ., Q; where Q is a total number of time periods,

where k=1, . . ., K; where K is a total number of events, and

where a_k and b_k are estimated logistic coefficients for event k

(step (d)). These limitations, when given their broadest reasonable interpretation, recite scheduling compliance inspections of pharmaceutical product manufacturing sites based on a risk score, calculated using a statistical model. Although claim 1 recites that the method steps are executed by a processor, the underlying processes recited in the claim are all acts that could be performed by a human, e.g., mentally or manually, using pen and paper, without the use of a computer or any other machine. For example, a person could receive, via oral or written communication, data relating to a plurality of pharmaceutical product manufacturing sites. Such a person, using pen and paper, also could calculate a risk score, for each of the plurality of manufacturing sites, and could schedule compliance inspections of the manufacturing sites based on the calculated risk scores, via either written or oral communication. Simply put, claim 1 recites a mental process, i.e., a concept performed in the human mind, including an evaluation or judgment, and therefore, an abstract idea. *See* 2019 Revised Guidance, 84 Fed. Reg. at 52; *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1373 (Fed. Cir. 2011) (holding that method steps that can be performed in the human mind, or by a human using a pen and paper, are unpatentable mental processes). *See also Elec. Power Grp., LLC v. Alstom, S.A.*, 830 F.3d 1350, 1355 (Fed. Cir. 2016) (explaining that the Federal Circuit treats "analyzing information by steps people go through in their minds, or by mathematical algorithms, without more, as essentially mental processes within the abstract-idea category"); *Versata Dev. Grp., Inc. 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.").

Having concluded that claim 1 recites a judicial exception, i.e., an abstract idea (Step 2A, Prong One), we next consider whether the claim recites additional elements that integrate the judicial exception into a practical application (Step 2A, Prong Two).

The only additional elements recited in claim 1, beyond the abstract idea, are a computer readable medium having instructions stored thereon and a processor that executes the stored instructions — elements recited at a high level of generality, and described in the Specification as generic computer components (*see, e.g.*, Spec. ¶¶ 24, 25, 45). We find no indication in the Specification, nor does Appellant direct us to any indication, that the operations recited in claim 1 invoke any assertedly inventive programming, require any specialized computer hardware or other inventive computer components, i.e., a particular machine, or that the claimed invention is implemented using other than generic computer components to perform generic computer functions. *See DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1256 (Fed. Cir. 2014) ("[A]fter *Alice*, there can remain no doubt: recitation of generic computer limitations does not make an otherwise ineligible claim patent-eligible.").

We also find no indication in the Specification that the claimed invention effects a transformation or reduction of a particular article to a different state or thing. Nor do we find anything of record that attributes an improvement in technology and/or a technical field to the claimed invention or that otherwise indicates that the claimed invention integrates the abstract

idea into a "practical application," as that phrase is used in the 2019 Revised Guidance.[6]

Appellant asserts that "the recitations of claim 1 plainly include a computer generated statistical model that leverages a probability function to predict risk at various manufacturing sites" (Appeal Br. 8). And Appellant ostensibly maintains that claim 1 is not directed to an abstract idea because "the machine performed risk prediction from claim 1 is achieved with steps that are more complicated than a human would perform" (*id.* at 11). Appellant argues that "a human would not generate . . . a statistical model that includes a regression relationship between observed events and risk parameters when predicting a risk at these manufacturing sites, as this technique is the way machines perform predictions, not humans" (*id.*). Yet, aside from the recitation that the method steps are executed by a processor, we find nothing in the claim language that forecloses the claimed steps from being performed by a human, mentally or with pen and paper. In this regard, we agree with the Examiner that "though less efficient, one of ordinary skill in the art could reduce the recited mathematical operations comprising exponential multiplication, division, and subtraction to pen and paper by employing human cognition. That is to say, a human can calculate a logistic regression like a computer, albeit less efficiently" (Final Act. 16–17).

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[6] The 2019 Revised Guidance references MPEP § 2106.05(a)–(c) and (e) in listing considerations that are indicative that an additional element or combination of elements integrates the judicial exception, e.g., the abstract idea, into a practical application. 2019 Revised Guidance, 84 Fed. Reg. at 55. If the recited judicial exception is integrated into a practical application, as determined under one or more of these MPEP sections, the claim is not "directed to" the judicial exception.

That a computer may be required is, moreover, an insufficient basis to persuasively argue that claim 1 is not directed to an abstract idea. Indeed, a substantially similar argument was expressly rejected by the Court in *Alice*. Thus, although the claimed invention in *Alice* involved a computer system acting as a third-party intermediary between two parties — "As stipulated, the claimed method requires the use of a computer to create electronic records, track multiple transactions, and issue simultaneous instructions; in other words, '[t]he computer is itself the intermediary,'" *Alice Corp.*, 573 U.S. at 224 — the Court held that "the claims at issue amount to 'nothing significantly more' than an instruction to apply the abstract idea of intermediated settlement using some unspecified, generic computer." *Id.* at 225–26. *See also FairWarning IP, LLC v. Iatric Systems, Inc.*, 839 F.3d 1089, 1098 (Fed. Cir. 2016) ("the inability for the human mind to perform each claim step does not alone confer patentability. As we have explained, 'the fact that the required calculations could be performed more efficiently via a computer does not materially alter the patent eligibility of the claimed subject matter.'") (citation omitted); *In re TLI Commc'ns LLC Patent Litig.*, 823 F.3d 607, 611 (Fed. Cir. 2016) ("[N]ot every claim that recites concrete, tangible components escapes the reach of the abstract-idea inquiry.").

Similarly here, the computer implementation is purely generic and performs generic computer functions, i.e., receiving and processing information. As described above, there is no indication in the Specification that any inventive computer components or specialized computer hardware is required. Instead, it is clear from the Specification that the claimed invention is implemented using generic computer components (*see, e.g.*, Spec. ¶ 24), which the Court made clear in *Alice* is insufficient to transform

an otherwise patent-ineligible abstract idea into patent-eligible subject matter. *Alice Corp.*, 573 U.S. at 223 (holding that if a patent's recitation of a computer amounts to a mere instruction to implement an abstract idea on a computer, that addition cannot impart patent eligibility).

We also do not agree with Appellant that there is any parallel between claim 1 and the claims at issue in *McRO, Inc. v. Bandai Namco Games America, Inc.*, 837 F.3d 1299, 1312 (Fed. Cir. 2016) (Appeal Br. 12–14; *see also* Reply Br. 8–10). Claim 1 of the '576 patent,[7] at issue in *McRO*, is directed to a method for automatically animating the lip synchronization and facial expressions of three-dimensional animated characters, and recites that the method comprises, *inter alia*, "obtaining a first set of rules that define output morph weight set stream as a function of phoneme sequence and time of said phoneme sequence." *McRO*, 837 F.3d at 1307–08. The Federal Circuit determined that the claim, when considered as a whole, is directed to a technological improvement over existing, manual 3–D animation techniques, and uses limited rules in a process specifically designed to achieve an improved technological result relative to conventional industry practice. *Id.* at 1316. As such, the court determined that the claim is not directed to an abstract idea, and is patent eligible under 35 U.S.C. § 101. *Id.*

Appellant argues here that the pending claims are not directed to an abstract idea because, similar to the claim in *McRO*, the claims are directed to an improvement in the "space of machine prediction" (Appeal Br. 13). Appellant, thus, maintains that, similar to *McRO*, "the present claims recite the use of specific rules to improve the manner in which a computer

[7] U.S. Patent No. 6,307,576, issued October 23, 2001.

performs machine prediction" (*id.*). And Appellant cites the use of "a constructed statistical model, a specific [probability] function, and specific inputs" as providing improvements in the space of machine prediction (*id.*; *see also* Reply Br. 10 ("[T]he determined risk score and statistical model recited in the claims achieves inspection of pharmaceutical product manufacturing sites in a manner that is wholly different from convention.").

The difficulty with Appellant's argument is that it, at best, merely establishes that the statistical model, including the recited probability function, is a new and improved mathematical formula/algorithm, i.e., an improved abstract idea, for determining a risk score that corresponds to expected deficiencies that would be found if a particular pharmaceutical product manufacturing site was inspected. As the court observed in *SAP America, Inc. v. InvestPic, LLC*, 898 F.3d 1161 (Fed. Cir. 2018), the claims in *McRO* were directed to "the creation of something physical — namely, the display of 'lip synchronization and facial expressions' of animated characters on screens for viewing by human eyes" and "[t]he claimed improvement was to how the physical display operated (to produce better quality images)." *Id.* at 1167. Here, like the claims at issue in *SAP America* (which the court determined were directed to abstract ideas, i.e., selecting certain information, analyzing it using mathematical techniques, and reporting or displaying the results of the analysis), the claimed improvement is a "mathematical technique with no improved display mechanism." *Id.* However valuable or useful the statistical model may be in predicting manufacturing site deficiencies, its value or usefulness is not dispositive of patent eligibility. *See Parker v. Flook*, 437 U.S. 584, 594–95 (1978) (holding claims to "a new and presumably better method for calculating

alarm limit values," of undisputed usefulness, to be directed to patent-ineligible subject matter); *see also Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 591 (2013) ("Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry."). An improved abstract idea is still an abstract idea. *Cf. Mayo*, 566 U.S. at 90 (holding that a novel and nonobvious claim directed to a purely abstract idea is, nonetheless, patent ineligible).

It also is not controlling that claim 1 presents no risk of preemption (Appeal Br. 15; *see also id*. at 17). Although the Supreme Court has described "the concern that drives [the exclusion of abstract ideas from patent-eligible subject matter] as one of pre-emption," *Alice Corp.*, 573 U.S. at 216, characterizing preemption as a driving concern for patent eligibility is not the same as characterizing preemption as the sole test for patent eligibility. "The Supreme Court has made clear that the principle of preemption is the basis for the judicial exceptions to patentability" and "[f]or this reason, questions on preemption are inherent in and resolved by the § 101 analysis." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015) (citing *Alice Corp.*, 573 U.S. at 216). "[P]reemption may signal patent ineligible subject matter, [but] the absence of complete preemption does not demonstrate patent eligibility." *Id.*

Addressing the 2019 Revised Guidance, Appellant argues in the Reply Brief, that even if "abstract ideas were included in claim 1," the claim "recites a practical application of the statistical model recited in the claim" (Reply Br. 2–3). We disagree.

As described above, the 2019 Revised Guidance lists various considerations that are indicative that an additional element or combination

of elements integrates a judicial exception, e.g., an abstract idea, into a practical application. For example, a practical application may be reflected in an improvement in the functioning of a computer or an improvement to other technology or technical field, a particular machine or manufacture integral to the claim, or a transformation or reduction of an article to a different state or thing. *See* 2019 Revised Guidance, 84 Fed. Reg. at 55. However, merely using a computer as a tool to perform an abstract idea, adding insignificant extra-solution activity, or only generally linking the use of a judicial exception to a particular technological environment or field are not sufficient to integrate the judicial exception into a practical application. *See id.*

Appellant asserts here that "the functionality of the additional elements of 'scheduling the compliance inspections of the pharmaceutical product manufacturing sites by the pharmacovigilance team based on the determined risk score'" such that product manufacturing sites that have a higher estimated level of risk are scheduled before pharmaceutical product manufacturing sites that have a lower estimated level of risk, as recited in claim 1, "integrates the claimed risk score and statistical model into a practical application" that "improves upon the inspection of pharmaceutical product manufacturing sites by integrating sophisticated modeling and machine prediction techniques into the inspections" (Reply Br. 3–4). And Appellant argues that "[t]his specific integration imposes meaningful limits on the risk score and/or statistical model, such that the claim is more than a drafting effort designed to monopolize the risk score/statistical model" (*id.* at 4). Yet, without the risk score and statistical model, claim 1 would be reduced, per Appellant's characterization of the "additional elements," to

mere data gathering — "receiving data relating to a plurality of pharmaceutical product manufacturing sites" — in other words, to "insignificant extra-solution activity" (*see* Ans. 4)[8] and merely linking the use of the judicial exception, i.e., the statistical model, to a particular field of use, i.e., scheduling inspections of pharmaceutical product manufacturing sites[9] — considerations indicative that an additional element or combination of elements does *not* integrate the judicial exception into a practical application.

Appellant cites Examples 40 and 42 of the USPTO's "Subject Matter Eligibility Examples: Abstract Ideas" issued January 7, 2019 (the "2019 Examples") [10] as supporting its position (Reply Br. 4–7). Yet, rather than paralleling hypothetical claims 1 in Examples 40 and 42, pending claim 1, in our view, is akin to hypothetical claims 2 of these examples, which the USPTO concluded were patent ineligible. Here, as in hypothetical claims 2,

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[8] *See* 2019 Revised Guidance, 84 Fed. Reg. at 55 n.31; *see also Bilski v. Kappos*, 561 U.S. 593, 612 (2010) (holding the use of well-known techniques to establish inputs to the abstract idea as extra-solution activity that fails to make the underlying concept patent eligible); *Bancorp Servs, L.L.C. v. Sun Life Assur. Co. of Can.*, 771 F. Supp. 2d 1054, 1066 (E.D. Mo. 2011) *aff'd*, 687 F.3d 1266 (Fed. Cir. 2012) (explaining that "storing, retrieving, and providing data . . . are inconsequential data gathering and insignificant post solution activity").

[9] Although we consider the steps of "receiving data relating to a plurality of pharmaceutical product manufacturing sites" and "scheduling the compliance inspections of the pharmaceutical product manufacturing sites by the pharmacovigilance team based on the determined risk score" as part of the abstract idea itself, for the limited purpose of addressing Appellant's argument, we alternatively treat these steps as "additional elements."

[10] Available at https://www.uspto.gov/sites/default/files/documents/101_examples_37to42_20190107.pdf.

the additional elements, as identified by Appellant, amount to mere data gathering, i.e., insignificant extra-solution activity, or are no more than mere instructions to apply the judicial exception using a generic computer component. *See* 2019 Examples 11–13, 19–20. As such these additional elements do not integrate the judicial exception into a practical application. *Id.*

We also are not persuaded of Examiner error to the extent Appellant maintains that claim 1 is not directed to an abstract idea and is analogous to the claims that the Court upheld as patent eligible in *Diamond v. Diehr*, 450 U.S. 175 (1981) (Reply Br. 7–8). The claims in *Diehr* were directed to a process for curing synthetic rubber, and recited a series of steps (e.g., the loading of a molding press with raw, uncured rubber, closing the press, constantly determining the mold temperature, constantly recalculating the cure time, and automatically opening the press at the proper time) that together provided a significant and novel practical application of the well-known Arrhenius equation and transformed uncured synthetic rubber into a new state or thing. *See Diehr*, 450 U.S. at 184–87. In holding the claims patent eligible, the Court explained:

> [W]e think that a physical and chemical process for molding precision synthetic rubber products falls within the § 101 categories of possibly patentable subject matter. That respondents' claims involve the transformation of an article, in this case raw, uncured synthetic rubber, into a different state or thing cannot be disputed. The respondents' claims describe in detail a step-by-step method for accomplishing such, beginning with the loading of a mold with raw, uncured rubber and ending with the eventual opening of the press at the conclusion of the cure. Industrial processes such as this are the types which have historically been eligible to receive the protection of our patent laws.

Id. at 184. Appellant asserts here that just as "the inclusion of the mathematical formula did not render [the] claim at issue in *Diehr* directed towards an abstract idea, as the mathematical formula was part of a larger process," claim 1 "implements the statistical model within a practical application, namely the scheduling of inspections of pharmaceutical product manufacturing sites by the pharmacovigilance team based on the determined risk score/statistical model" (Reply Br. 8). We, however, fail to see how scheduling inspections of pharmaceutical product manufacturing sites is similar to controlling a physical process like the process in *Diehr*. Claim 1 does not involve any "industrial" or "physical and chemical process" and does not involve the "transformation of an article . . . into a different state or thing."

We conclude, for the reasons outlined above, that claim 1 recites a mental process, i.e., an abstract idea, and that the additional elements recited in the claim are no more than generic computer components used as tools to perform the recited abstract idea. As such, they do not integrate the abstract idea into a practical application. *See Alice Corp.*, 573 U.S. at 223–24 ("[W]holly generic computer implementation is not generally the sort of 'additional featur[e]' that provides any 'practical assurance that the process is more than a drafting effort designed to monopolize the [abstract idea] itself.'" (quoting *Mayo*, 566 U.S. at 77)). Accordingly, we agree with the Examiner that claim 1 is directed to an abstract idea.

Step Two of the Mayo/Alice Framework (*2019 Revised Guidance, Step 2B*)

Having determined under step one of the *Mayo*/*Alice* framework that claim 1 is directed to an abstract idea, we next consider under Step 2B of the 2019 Revised Guidance, the second step of the *Mayo*/*Alice* framework,

whether claim 1 includes additional elements or a combination of elements that provides an "inventive concept," i.e., whether the additional elements amount to "significantly more" than the judicial exception itself.
2019 Revised Guidance, 84 Fed. Reg. at 56.

Appellant argues that even if claim 1 is directed to an abstract idea, the claim is nonetheless patent eligible because "the ordered combination recited in the claim renders the claim significantly more than any abstract idea" (Appeal Br. 18). Appellant attempts to draw an analogy between claim 1 and the claims at issue in *BASCOM Global Internet Services, Inc. v. AT&T Mobility LLC*, 827 F.3d 1341 (Fed. Cir. 2016) (*id.* at 18–19). But, we find no parallel between claim 1 and the claims at issue in *BASCOM*.

In *BASCOM*, the Federal Circuit determined that the claimed installation of a filtering tool at a specific location, remote from the end-users, with customizable filtering features specific to each end user provided an inventive concept in that it gave the filtering tool both the benefits of a filter on a local computer and the benefits of a filter on the ISP server. *BASCOM*, 827 F.3d at 1350. And the court held that the second step of the *Mayo*/*Alice* framework was satisfied because the claimed invention "represents a 'software-based invention[ ] that improve[s] the performance of the computer system itself.'" *Id.* at 1351 (stating that like *DDR Holdings*, where the patent "claimed a technical solution to a problem unique to the Internet," the patent in *BASCOM* claimed a "technology-based solution . . . to filter content on the Internet that overcomes existing problems with other Internet filtering systems . . . making it more dynamic and efficient") (internal citations omitted).

Appellant asserts here that claim 1 recites "specific improvements to computer technology" (Appeal Br. 19). Yet, Appellant does not identify, and we do not find, any improvement to computer technology analogous to the ordered combination described in *BASCOM* or any additional element or elements recited in claim 1 that yield an improvement in the functioning of a computer.

Appellant paraphrases the language of claim 1 (*id.* at 18–19). And Appellant argues that "this ordered combination of elements improves the manner in which machine prediction of risk is performed" and, "similar to the claims in *Bascom*, . . . recites significantly more than any alleged abstract idea" (*id.* at 19). Yet, the limitations to which Appellant refers, including "estimating a plurality of hyper-parameters" and "determining a risk score . . . based on a statistical model," are part of the abstract idea itself; they are not additional elements to be considered when determining whether claim 1 includes additional elements or a combination of elements that is sufficient to amount to significantly more than the judicial exception.

It could not be clearer from *Alice*, that under step two of the *Mayo*/*Alice* framework, the elements of each claim are considered both individually and "as an ordered combination" to determine whether the additional elements, i.e., the elements *other* than the abstract idea itself, "transform the nature of the claim" into a patent-eligible application. *Alice Corp.*, 573 U.S. at 217 (internal quotations and citation omitted); *see Mayo*, 566 U.S. at 72–73 (requiring that "a process that focuses upon the use of a natural law also contain *other* elements or a combination of elements, sometimes referred to as an 'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent

upon the natural law itself") (emphasis added). In other words, the inventive concept under step two of the *Mayo*/*Alice* framework cannot be the abstract idea itself:

> It is clear from *Mayo* that the "inventive concept" cannot be the abstract idea itself, and *Berkheimer* . . . leave[s] untouched the numerous cases from this court which have held claims ineligible because the only alleged "inventive concept" is the abstract idea.

Berkheimer v. HP, Inc., 890 F.3d 1369, 1374 (Fed. Cir. 2018) (Moore, J., concurring); *see also BSG Tech*, 899 F.3d at 1290 ("It has been clear since *Alice* that a claimed invention's use of the ineligible concept to which it is directed cannot supply the inventive concept that renders the invention 'significantly more' than that ineligible concept.") (internal citation omitted).

The only claim elements recited in claim 1 beyond the abstract idea are the computer readable medium having instructions stored thereon, and the processor that executes the stored instructions, i.e., generic computer components used to perform generic computer functions — a determination amply supported by, and fully consistent with, the Specification (*see, e.g.*, Spec. ¶ 24).[11] Appellant cannot reasonably contend, nor does Appellant, that the operation of these components is not well-understood, routine, or

[11] The Office's April 19, 2018 Memorandum to the Examining Corps from Deputy Commissioner for Patent Examination Policy, Robert W. Bahr, entitled, Changes in Examination Procedure Pertaining to Subject Matter Eligibility, Recent Subject Matter Eligibility Decision (*Berkheimer v. HP, Inc.*), available at https://www.uspto.gov/sites/default/files/documents/memo-berkheimer-20180419.PDF, expressly directs that an examiner may support the position that an additional element (or combination of elements) is well-understood, routine or conventional with "[a] citation to an express statement in the specification . . . that demonstrates the well-understood, routine, conventional nature of the additional element(s)" (*id.* at 3).

conventional, where, as here, there is nothing in the Specification to indicate that the operations recited in claim 1 require any specialized hardware or inventive computer components, invoke any assertedly inventive software, or that the claimed invention is implemented using other than generic computer components to perform generic computer functions, e.g., receiving, transmitting, and processing information.[12]

We are not persuaded, on the present record, that the Examiner erred in rejecting independent claim 1 under 35 U.S.C. § 101. Therefore, we sustain the Examiner's rejection of claim 1, and dependent claims 4, 19, and 21, which are not argued separately except based on their dependence from claim 1 (Appeal Br. 22–23).

Independent Claims 7 and 13 and Dependent Claims 10, 16, 20, and 22–24

Appellant argues that independent claims 7 and 13 are patent eligible for reasons similar to those set forth with respect to claim 1 (*id.*). We are not persuaded for the reasons set forth above that the Examiner erred in rejecting claim 1 under 35 U.S.C. § 101. Therefore, we sustain the Examiner's rejection of claims 7 and 13 for the same reasons. We also sustain the

[12] Appellant argues that "per *Berkheimer*, the additional elements for which evidence must be provided include the functional elements beyond the mere hardware components" (Reply Br. 12). It is not entirely clear to what "functional elements" Appellant refers. However, to the extent, Appellant maintains that evidence is required to establish the well-understood, routine, conventional nature of "receiving data relating to a plurality of pharmaceutical product manufacturing sites" and "scheduling the compliance inspections," we note that receiving data is a routine and conventional activity which virtually any generic computing device can perform and that the well-understood, routine, and conventional nature of scheduling compliance inspections is evident from Appellant's own Specification (*see, e.g.*, Spec. ¶¶ 2-4).

rejection of dependent claims 10, 16, 20, and 22–24, which are not argued separately except based on their dependence from claims 7 and 13 (*id.*).

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s) /Basis	Affirmed	Reversed
1, 4, 6, 7, 10, 12, 13, 16, 18–24	101	Eligibility	1, 4, 6, 7, 10, 12, 13, 16, 18–24	

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