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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte FREDERIC J. HUSER

Appeal 2018-001224
Application 14/860,248[1]
Technology Center 3600

Before ROBERT E. NAPPI, ERIC S. FRAHM, and MICHAEL T. CYGAN, *Administrative Patent Judges*.

FRAHM, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[2] appeals from the Examiner's decision to reject claims 1–15 and 18–25, which constitute all the claims pending in this application. Claims 16 and 17 have been canceled (*see* Final Act. 2). We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

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[1] The instant application on appeal is a continuation application of U.S. Patent Application Serial No. 13/771,704, abandoned on February 20, 2013, which claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Application 61/601,308 filed February 21, 2012 (*see* Spec. ¶ 1).

[2] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. "The word 'applicant' when used in this title refers to the inventor or all of the joint inventors, or to the person applying for a patent as provided in §§ 1.43, 1.45, or 1.46." Appellant identifies the real party in interest as the inventor, Frederic J. Huser (Appeal Br. 2).

STATEMENT OF THE CASE

Disclosed Invention and Exemplary Claim

According to Appellant, the present invention "provides a process for making [a] drug available to the public as an over-the-counter [OTC] medication, with certain restrictions that the inventor believes would be acceptable to both FDA and the drug manufacturer/distributor" (Appeal Br. 16). More specifically, Appellant discloses the claimed method as useful and applicable for drugs with "a long-standing need for an Rx-to-OTC switch" (Spec. ¶ 5), for example, "cholesterol drugs such as lovastatin and pravastatin" (*id.*; *see also id.* ¶¶ 5, 6, 8, 56), and diabetes and hypertension drugs (*see id.* ¶ 56). According to Appellant:

> A significant public health benefit could be derived if these medications were accessible in a more convenient, more widespread OTC purchase environment. Further, if prescription drugs for chronic conditions can be made more broadly and more inexpensively available with appropriate safeguards, then the population will have better access to these drugs and be healthier overall.

(*Id.* ¶ 15.)

> [T]he diagnostic actions will be administered only at the point of sale ("POS") in Food, Drug, or Mass Merchandiser stores which have Clinical Laboratories Improvement Act ("CLIA") certificates of waiver from the appropriate state and/or federal regulatory body to conduct CLIA-waived diagnostic tests with trained healthcare personnel present (such as those in a pharmacy) and will be conducted by retail store healthcare personnel to determine before drug use the presence of the chronic condition and to determine after drug use drug effectiveness and safety in the individual patient.

(*Id.* ¶ 1.)

Exemplary independent claim 1 under appeal recites a method of offering a drug for sale as an OTC product based on real-time diagnostic results at a point-of-sale location, and is reproduced below with *emphases* and bracketed lettering added to key portions of the claim at issue:

> 1. *A method of offering for sale a drug* as an over-the-counter (OTC) product based on the real time diagnostic results at a point-of-sale location from a specific CLIA-waived diagnostic test identified in a condition-of-use label for the drug, comprising
>
> [A] administering a specific CLIA-waived diagnostic test to a human patient by having a healthcare person obtain a fluid sample from the patient at a point-of-sale location,
>
> [B] testing the fluid sample in the specific CLIA-waived diagnostic machine at the point-of-sale location, wherein the CLIA-waived diagnostic machine analyzes the fluid sample and delivers results in less than 30 minutes regarding a biomarker,
>
> [C] <u>determining whether the human patient is a candidate for treatment with a drug</u> by having a healthcare person at the point-of-sale location analyze the results of the CLIA-waived diagnostic test <u>to determine if the biomarker is within a required range as indicated on the condition-of-use label</u>, and
>
> [D] *offering to the patient a drug regimen comprising a plurality of unit doses of the drug* <u>only if the results of the diagnostic test indicate that the patient would benefit from treatment with the drug</u>.

Appeal Br., Appendix A, A1 (emphases and bracketed lettering added). Remaining independent claim 15 recites a method of treating a human patient on an OTC basis with a drug having limitations commensurate in scope with limitations [A]–[D] of claim 1.

The Examiner's Rejections

(1) Claims 1, 4, and 24 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter (a human being) (Final Act. 2–3).

Because this rejection has been withdrawn by the Examiner (*see* Ans. 2), we do not consider it further herein.

(2) Claims 1–15 and 18–25 stand rejected under 35 U.S.C. § 101 as being directed to patent-ineligible subject matter (an abstract idea) (Final Act. 3–6).

(3) Claims 1–15 and 18–25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Keravich et al. (US 2009/0125324 A1; published May 14, 2009) (hereinafter, "Keravich") and Appellant's Admitted Prior Art found at paragraphs 58 and 59 of the Specification (hereinafter, "AAPA") (Final Act. 7–21).

Appellant's Contentions

(1) Appellant contends (Appeal Br. 11–23; Reply Br. 4–15) that the Examiner erred in rejecting claims 1–15 and 18–25 under 35 U.S.C. § 101. Specifically, Appellant contends the claims are not directed to an abstract idea (Appeal Br. 11–17; Reply Br. 4–11) and the claimed invention amounts to significantly more than an abstract idea (Appeal Br. 17–23; Reply Br. 14–15). Appellant primarily presents arguments as to independent claims 1 and 15 (Appeal Br. 11–23; Reply Br. 4–15), and asserts that the dependent claims include similar limitations as claims 1 and 15 and are, therefore, patent eligible for the same reasons. Both method claims 1 and 15 contain commensurate limitations and are argued for similar reasons. Therefore, with regard to the patent-eligibility rejection, we select claim 1 as representative of the group of claims 1–15 and 18–25 pursuant to our authority under 37 C.F.R. § 41.37(c)(1)(iv).

(2) Appellant contends (Appeal Br. 23–33; Reply Br. 15–22) that the Examiner erred in rejecting claims 1–15 and 18–25 under 35 U.S.C.

§ 103(a). Appellant generally contends that Keravich teaches away from the claimed invention (Appeal Br. 25–26; Reply Br. 17, 19–21), because Keravich seeks to avoid interaction of a healthcare person at a point of sale, whereas the recited invention requires the intervention of health care personnel, in the offering for sale of a drug (*see* Appeal Br. 25). Appellant also contends the Examiner's motivation for combining Keravich and AAPA is insufficient and uses impermissible hindsight (*see* Appeal Br. 26; Reply Br. 19).

Principal Issues on Appeal

Based on Appellant's arguments in the Appeal Brief (Appeal Br. 11–33) and Reply Brief (Reply Br. 4–22), the following principal issues are presented on appeal:

(1) Has Appellant shown the Examiner erred in rejecting claims 1–15 and 18–25 under 35 U.S.C. § 101 as being directed to patent-ineligible subject matter, because representative claim 1 is directed to an abstract idea that is not patent eligible, without significantly more?

(2) Has Appellant shown the Examiner erred in rejecting claims 1–15 and 18–25 under 35 U.S.C. § 103(a) because Keravich teaches away from the invention recited in claim 1?

ANALYSIS

Issue (1): Patent Eligibility Under 35 U.S.C. § 101

We have reviewed the Examiner's (i) Final rejection (Final Act. 3–6); and (ii) Advisory Action mailed February 17, 2017 ("Adv. Act." 2), in light of Appellant's contentions in the Briefs that the Examiner erred (Appeal Br. 11–23; Reply Br. 4–15), as well as the Examiner's response to Appellant's

arguments in the Appeal Brief (*see* Ans. 3–13), and the evidence of record. We are not persuaded by Appellant's contentions that the Examiner erred in rejecting claims 1–15 and 18–25 under 35 U.S.C. § 101 as being directed to patent-ineligible subject matter, without significantly more. With regard to representative claim 1 rejected under 35 U.S.C. § 101, we adopt as our own (1) the findings and reasons set forth by the Examiner in the Final Office Action from which this appeal is taken (Final Act. 3–6), as well as the Advisory Action mailed February 17, 2017 (Adv. Act. 2); and (2) the reasons set forth by the Examiner in the Examiner's Answer (Ans. 3–13) in response to Appellant's Appeal Brief. We concur with the conclusions reached by the Examiner, and add the following for emphasis.

Section 101 of the Patent Act provides "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 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*. *Alice*, 573 U.S. 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, 67 (1972)). Concepts determined to be patent eligible include physical and chemical processes, such as "molding rubber products" (*Diamond v. Diehr*, 450 U.S. 175, 191 (1981)); "tanning, dyeing, making water-proof cloth, vulcanizing India rubber, smelting ores" (*id.* at 182 n.7 (quoting *Corning v. Burden*, 56 U.S. (15 How.) 252, 267–68 (1853))); and manufacturing flour (*Benson*, 409 U.S. at 69 (citing *Cochrane v. Deener*, 94 U.S. 780, 785 (1876))).

In *Diehr*, the claim at issue recited a mathematical formula, but the Supreme Court held that "a claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula." *Diehr*, 450 U.S. at 187; *see also id.* at 191 ("We view respondents' claims as nothing more than a process for molding rubber products and not as an attempt to patent a mathematical formula."). Having said that, the Supreme Court also indicated that a claim "seeking patent protection for that formula in the abstract . . . is not accorded the protection of our patent laws, and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment." *Id.* (citing *Benson* and *Flook*); *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 (internal 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.* (alterations in original) (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 (Jan. 7, 2019) ("Guidance"). Under the 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) (Step 2A, Prong 1); and
>
> (2) additional elements that integrate the judicial exception into a practical application (*see* MANUAL OF PATENT EXAMINING PROCEDURE ("MPEP") §§ 2106.05(a)–(c), (e)–(h)) (9th Ed., Rev. 08.2017, 2018) (Step 2A, Prong 2).

Only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application, do we then look to whether the claim:

> (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 (Step 2B).

See Guidance, 84 Fed. Reg. at 54–56.

Even if the claim recites an abstract idea, the Federal Circuit explains the "directed to" inquiry is not simply asking whether the claims involve a patent-ineligible concept:

> The "directed to" inquiry . . . cannot simply ask whether the claims *involve* a patent-ineligible concept, because essentially every routinely patent-eligible claim involving physical products and actions *involves* a law of nature and/or natural phenomenon—after all, they take place in the physical world. *See Mayo*, [566 U.S. at 71] ("For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.") Rather, 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); *see also Diehr*, 450 U.S. at 188 ("In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole."); *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1314 (Fed. Cir. 2016) (The question is whether the claims as a whole "focus on a specific means or method that improves the relevant technology or are instead directed to a result or effect that itself is the abstract idea and merely invoke generic processes and machinery").

Step 1

Under Step 1 of the patent-eligibility inquiry under § 101, we determine whether a claim is directed to one of the four statutory categories of invention, i.e., a process, machine, manufacture, or composition of matter.

In the instant case on appeal, independent claims 1 and 15, as well as claims 2–14 and 18–25 depending respectively therefrom, each recite "[a] method of offering for sale a drug" (claims 1–14, 22) or "[a] method of treating a human patient on an over-the-counter (OTC) basis with a drug" (claims 15, 18–21, 23–25) having several steps for performing a series of acts, for example, administering a point-of-sale, CLIA-waived diagnostic test of a human patient, determining if the human patient is a candidate for treatment, and "offering to the patient a drug regimen" (claims 1, 15). Therefore, claims 1 and 15, and claims 2–14 and 18–25 depending respectively therefrom, as method claims, recite at least one of the enumerated categories (e.g., process) of eligible subject matter in 35 U.S.C. § 101.

As a result, as to claims 1–15 and 18–25, we continue our analysis under Step 2A, Prong 1 of the Guidance to determine whether the claims (1) recite a judicial exception (a law of nature, natural phenomenon, or subject matter within the enumerated groupings of abstract ideas above); and (2) are patent-eligible.

Step 2A, Prong 1

At a high level, representative claim 1 recites a method of offering for sale a drug after determining if a patient would benefit from treatment with the drug. According to Appellant, the present invention "provides a process for making [a] drug available to the public as an over-the-counter [(OTC)]

medication, with certain restrictions that the inventor believes would be acceptable to both FDA and the drug manufacturer/distributor" (Appeal Br. 16).

The preamble and limitation [D] of the claim 1 are *focused on*, and generally relate to, commercial/sales activities, i.e., offering a drug for sale, which is a business relation between people (e.g., a patient/customer and a pharmacy/seller/healthcare person or other business entity) (*see generally* Spec. ¶¶ 2–7). As such, the claimed invention recites certain methods of organizing human activity, which is an abstract idea. The Examiner determines, and we agree, that claim 1 is "drawn to a method for offering for sale a drug as an over-the-counter product" (Final Act. 3), and '"offering for sale a drug based on real diagnostic results'" (Ans. 3). Limitations [A] and [B] are routine data gathering steps, and recite a process for a healthcare person to administer a diagnostic test to a human patient by obtaining a fluid sample from a patient for testing of the fluid sample by a diagnostic machine which outputs biomarker results. In limitation [C], a healthcare person analyzes the test results to determine if the patient is a candidate for treatment, and in limitation [D], a drug regimen is offered to the patient if the test results indicate the patient would benefit, which are mental processes involving evaluation and judgment. Finally, the correlation between (i) determining if the patient is a candidate for treatment based on the biomarker results being within a required range as set forth in limitation [C]; and (ii) the patient being benefited from treatment with the drug as set forth in limitation [D], describes a natural law.

The method of offering a drug regimen in claim 1 of the instant case has many similarities to the method of treatment found patent ineligible in

Mayo. In *Mayo*, the Supreme Court found that claims covering laws of nature, such as effective drug treatment regimens/dosages, are not patent eligible. *Mayo*, 566 U.S. at 70. Similar to claim 1 in the instant case before us, "the steps in the claimed processes [in *Mayo*] (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field" (*id.* at 73). As stated in *Mayo*, the claimed process steps "simply tell doctors to gather data from which they may draw an inference in light of the correlations" (*id.* at 79). Limitations [A] and [B] set forth in claim 1 of the instant case are no different – data is gathered in order to assist a healthcare person analyze the results in limitation [C] in order to determine if the patient would benefit from treatment with the drug before offering a drug regimen to the patient in limitation [D]. In the words of the Supreme Court in *Mayo*:

> To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.

Id. at 79–80.

Moreover, but for the recitation of a "specific CLIA-waived diagnostic machine at the point-of-sale location" used for "administering a specific CLIA-waived diagnostic test to a human patient" (*see* claim 1, preamble, limitations [A] and [B]), we find the recited steps or acts, could be performed as mental steps, or with the aid of pen and paper, by the recited "healthcare person" (claim 1, limitation [C]). *See CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 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*.").

Our reviewing court has concluded that abstract ideas include the concepts of collecting data, recognizing certain data within the collected data set, and storing the data in memory. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1366 (Fed. Cir. 2018) (concluding that the acts of parsing, comparing, storing, and editing data are abstract ideas); *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n*, 776 F.3d 1343, 1347 (Fed. Cir. 2014) (abstract ideas include the concepts of collecting data, recognizing certain data within the collected data set, and storing the data in memory); *see also Smart Sys. Innovations, LLC v. Chicago Transit Auth.*, 873 F.3d 1364, 1372 (Fed. Cir. 2017) (concluding "claims directed to the collection, storage, and recognition of data are directed to an abstract idea"). Therefore, claim 1, which recites collecting and recognizing certain data (limitations [A]–[C]), sets forth concepts recognized by our reviewing court to be judicially excepted abstract ideas that are patent ineligible.

Moreover, the further-recited acts of (i) comparing data, such as the biomarker comparison to a range recited in limitation [C]; and (ii) offering the patient a drug regimen recited in limitation [D], are acts of observation and evaluation that can be practically performed in the human mind, and are therefore abstract ideas. 84 Fed. Reg. at 52. With regard to the biomarker and range determination/comparison recited in limitation [C], collection of information and analysis of information (e.g., recognizing certain data within the dataset) are abstract ideas. *Elec. Power*, 830 F.3d at 1353. And, with regard to both limitations [C] and [D], our conclusion that these acts are part of an abstract mental process is further supported by case law. *See*

Berkheimer, 881 F.3d at 1366 (concluding that acts of parsing, comparing, storing, and editing data are abstract ideas); *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1167 (Fed. Cir. 2018)) ("[M]erely presenting the results of abstract processes of collecting and analyzing information . . . is abstract as an ancillary part of such collection and analysis."); *Intellectual Ventures I LLC v. Capital One Fin. Corp.*, 850 F.3d 1332, 1340 (Fed. Cir. 2017) ("collecting, displaying, and manipulating data" is an abstract idea); *Digitech Image Techs., LLC v. Elecs. for Imaging, Inc.*, 758 F.3d 1344, 1351 (Fed. Cir. 2014) (holding that, without additional limitations, a process that starts with data, applies an algorithm, and ends with a new form of data is directed to an abstract idea).

Further, merely combining several abstract ideas (such as a mathematical concept and a mental process) does not render the combination any less abstract. *RecogniCorp, LLC v. Nintendo Co.*, 855 F.3d 1322, 1327 (Fed. Cir. 2017) ("Adding one abstract idea . . . to another abstract idea . . . does not render the claim non-abstract."); *see also FairWarning IP, LLC v. Iatric Sys., Inc.*, 839 F.3d 1089, 1094 (Fed. Cir. 2016) (determining the pending claims were directed to a combination of abstract ideas).

In this light, the method for offering for sale a drug to a patient, including determining if treatment is beneficial based on test results and analysis of a biomarker delivered from testing a fluid sample recited in claim 1, describes (1) a law of nature; (2) certain methods of organizing human activity such as a fundamental economic practice like offering a drug for sale; combined with (3) a mental process involving concepts performed in the human mind (including an observation, evaluation, judgment, opinion) like analyzing test results. Thus, we conclude claim 1 recites (1) a method

of offering for sale a drug based on diagnostic results, through performance of (2) observations and judgments capable of being performed in the human mind, i.e., which is a mental process; and (3) applying laws of nature, based on the correlation between (i) determining if the patient is a candidate for treatment based on the biomarker results being within a required range, and (ii) the patient being benefited from treatment with the drug. In other words, claim 1 recites a *combination* of abstract ideas. We consider these limitations together to be the recited abstract idea for purposes of the eligibility analysis. October 2019 Patent Eligibility Guidance Update ("Update") at 2 (*available at* https://www.uspto.gov/sites/default/files/documents/peg_oct_2019_update.pdf). Claims 2–15 and 18–25 grouped with claim 1 contain similar subject matter, and similarly recite combinations of abstract ideas. Because we conclude independent claim 1 and claims 2–15 and 18–25 grouped therewith recite a combination of abstract ideas, we proceed to Step 2A, Prong 2 of the Guidance to determine whether claim 1 is "directed to" the judicial exception, by determining whether additional elements of the claim integrate the abstract idea into a practical application. Such additional elements may reflect an improvement to a technology or technical field. *See* Guidance, 84 Fed. Reg. at 55.

Step 2A, Prong 2 – Practical Application

Under Step 2A, Prong 2, we determine whether the recited judicial exception is integrated into a practical application of that exception by (a) identifying whether there are any additional elements recited in the claim beyond the judicial exception(s); and (b) evaluating those additional elements individually and in combination to determine whether they integrate the exception into a practical application. If the recited judicial

exception is integrated into a practical application, the claim is not directed to the judicial exception. Thus, we determine whether the claims "focus on a specific means or method that improves the relevant technology" or are "directed to a result or effect that itself is the abstract idea and merely invoke generic processes and machinery." *McRO*, 837 F.3d at 1314.

Here, claim 1 recites the additional elements of "a drug," "a condition-of-use label," "a human patient," "a healthcare person," "a fluid sample," "a point-of-sale location," "a specific CLIA-waived diagnostic test," and a "specific CLIA-waived diagnostic machine" (claim 1). Considering claim 1 as a whole, none of the additional elements applies or uses the abstract idea in a meaningful way such that the claim as a whole is more than a drafting effort designed to monopolize the exception.

Appellant has not shown claim 1 recites additional elements that integrate the judicial exception into a practical application. In particular, Appellant has not shown the additional elements (e.g., the CLIA-waived diagnostic test machine) integrate the judicial exception into a practical application. Appellant contends (Reply Br. 10) s that the "condition-of-use label for the drug" recited in claim 1 is not merely an intended use of the method. Appellant further contends (*id.* at 13–14) that the label provides technical improvement in the form of improving compliance of patients with the requirements of a label of a drug, and improving public access of the drug, thereby confining the claims to a particular useful application of the abstract idea.

We are not persuaded Appellant has shown that the recited label provides any improvement to a technology. Appellant's alleged improvements relate to restricting which users may purchase drugs based on

the suitability of the drug for the user based upon an associated suitability test, and alleged reductions in cost due to the removal of a prescription requirement and its associated costs. Reply Br. 13. However, Appellant characterizes these alleged benefits as being due to regulatory change, rather than any particular technological improvement. *Id.* (a "mandatory" test; "the FDA should permit the switch"); Spec. ¶¶ 2 ("drug labeling is regulated by the U.S. Food and Drug Administration ('FDA'))," 3 ("[a]ll such combination [of drug with a particular test] labels heretofore approved by the FDA are for Rx drugs only)." Appellant further characterizes the improvement as providing "certain restrictions that the inventor believes would be acceptable to both FDA and the drug manufacturer/distributor." Appeal Br. 16. Accordingly, we agree with the Examiner's conclusion that the additional limitations of the claims provide an improvement to a technology or technical field. Ans. 13.

Additionally, the claimed invention administers and analyzes a test to generate a biomarker. The Supreme Court in *Mayo* has determined that steps of administering a drug to a patient in need of that drug merely defines the relevant audience, and is not sufficient to transform the nature of the claim into a patent-eligible claim. *Mayo*, 566 U.S. at 77–78. Further, the step of determining the level of a relevant marker in a patient, by whatever process the doctor or the laboratory wishes to use, is merely telling the practitioner to engage in well-understood, routine, conventional activity previously engaged in by those who work in the field, and as such, does not provide significantly more to the identified judicial exception. *Id.* The Court further stated that a limitation providing only that informing a medical practitioner of the relevant natural laws, while trusting them to use those

laws appropriately in their decision-making; e.g., by prescribing appropriate drugs for a condition, does not, without more, provide eligibility to an otherwise ineligible claim. *Id.* at 78. Thus, to the extent that the condition of use label informs the practitioner of the relevant drug, or the relevant test that may be applied, such is not considered to provide eligibility under *Mayo*. As such, based on the record before us, we determine that the claimed invention is not integrated into a practical application.

For the reasons discussed above, we conclude Appellant's claim 1 (and claims 2–15 and 18–25 grouped therewith) invokes generic diagnostic components merely as a tool in which the healthcare person applies the judicial exception and, thus, the abstract idea is not integrated into a practical application. Because claim 1 recites a judicial exception (laws of nature, the abstract idea of a method of organizing human activity and a mental process) that is not integrated into a practical application, in accordance with the Guidance, we conclude claim 1 and claims 2–15 and 18–25 grouped therewith, are directed to an abstract idea under Step 2A, and the eligibility analysis with regard to claims 1–15 and 18–25 proceeds to Step 2B.

Step 2B – Inventive Concept

Having determined claim 1 and claims 2–15 and 18–25 grouped therewith are directed to an abstract idea that is not integrated into a practical application, we now evaluate whether the additional elements add a specific limitation that is not well-understood, routine, or conventional activity in the field, or simply append well-understood, routine, conventional activities

previously known to the industry, specified at a high level of generality, to the abstract idea. *See* Guidance.

In the instant case on appeal, the additional elements recited in claim 1 do not "contain[] an 'inventive concept' sufficient to 'transform' the claimed abstract idea into a patent-eligible application." *Alice*, 573 U.S. at 221 (internal quotation marks omitted), or "include 'additional features' to ensure 'that the [claim] is more than a drafting effort designed to monopolize the [abstract idea].'" *Id.* (alterations in original) (quoting *Mayo*, 566 U.S. at 77). Instead, claim 1 merely recites well-understood, routine, or conventional activity in the field previously known to the industry, specified at a high level of generality, to the abstract idea.

For example, the "specific CLIA-waived diagnostic test to a human patient" obtained from a fluid sample of the patient recited in claim 1 is disclosed as being performed by a conventional and well-known device, such as "a POS, CLIA-waived diagnostic machine" (Spec. ¶ 58), or a "table-top diagnostic test equipment (the Piccolo Xpress)" which can deliver results "in under 15 minutes" (*id.* ¶ 59). Thus, we agree with the Examiner that (i) the claimed "CLIA-waived diagnostic machine is a well-known device that analyzes the tests for the patients and it[]s functions . . . are well-understood, routine and conventional activities previously known to the pertinent industry" (Final Act. 5; *see also* Ans. 11); and (ii) "[t]he claims do not include additional elements that are sufficient to amount to significantly more than the judicial exception because the additional elements when considered both individually and as an ordered combination do not amount to significantly more than the abstract idea" (Ans. 11). We also agree with the Examiner (*see id.* at 7–8) that paragraph 61 of Appellant's Specification

describes the Piccolo Xpress as being a well-known table-top diagnostic test machine routinely used in the healthcare field for analyzing patient fluid samples. Finally, Appellant discloses that the test machine itself is generic, and "[t]he present invention is not limited by any particular diagnostic test equipment," and "currently available diagnostic equipment other than that which is specifically described herein [(e.g., the Piccolo Express)] may be used" (Spec. ¶ 62).

Thus, Appellant's Specification only describes well-understood, routine, conventional computerized and diagnostic testing device components in a manner that indicates the components and the functions they perform were well-known in the art. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) (explaining that "a patent need not teach, and preferably omits, what is well known in the art"); *see also Intellectual Ventures I LLC v. Erie Indem. Co.*, 850 F.3d 1315, 1331 (Fed. Cir. 2017) ("The claimed mobile interface is so lacking in implementation details that it amounts to merely a generic component (software, hardware, or firmware) that permits the performance of the abstract idea, i.e., to retrieve the user-specific resources.").

Appellant further argues that obtaining the claimed "condition-of-use label," either as explicitly set forth in claim 15, or as allegedly inherently required in claim 1, is not routine, conventional, or well-understood.[3] Reply

[3] We note that Appellant has stated that the FDA has never issued a condition of use over the counter drug label requiring the use of a CLIA-waived diagnostic test for any drug. Reply Br. 11. Because it was not raised by the Examiner, we do not take a position on the issue of whether Appellant's Specification as filed demonstrates possession of obtaining such

Br. 12, 14. However, the step of obtaining a condition-of-use label is part of the abstract idea, and not an additional limitation to the abstract idea. Final Act. 4–5. An inventive concept "cannot be furnished by the unpatentable law of nature (or natural phenomenon or abstract idea) itself." *Genetic Techs. v. Merial L.L.C.*, 818 F.3d 1369, 1376 (Fed. Cir. 2016); *see also Alice*, 573 U.S. at 217 (citing *Mayo*, 566 U.S. at 78 (after determining that a claim is directed to a judicial exception, "we then ask, '**[w]hat else** is there in the claims before us?'") (emphasis added)); *RecogniCorp*, 855 F.3d at 1327 ("Adding one abstract idea (math) to another abstract idea (encoding and decoding) does not render the claim non-abstract").

Therefore, based on the record before us, we are not persuaded of error in the Examiner's determination that claim 1 is directed to patent-ineligible subject matter, without significantly more. Accordingly, we affirm the Examiner's decision to reject claim 1, as well as claims 2–15 and 18–25 grouped therewith, as directed to patent-ineligible subject matter.

Preemption

Appellant's arguments (Reply Br. 14–15), that the present claims do not block innovation and pose no risk of preemption for the field of prescription drugs that are switched to OTC status, are unpersuasive. Preemption is not the sole test for patent eligibility, and any questions on preemption in the instant case have been resolved by the Examiner's *Alice* analysis. As our reviewing court has explained: "questions on preemption are inherent in and resolved by the § 101 analysis," and, although "preemption may signal patent ineligible subject matter, the absence of

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a condition-of-use label at the time the application, or the provisional to which it claims priority, was filed.

complete preemption does not demonstrate patent eligibility." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015); *cf. OIP Techs. Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1362–63 (Fed. Cir. 2015) ("[T]hat the claims do not preempt all price optimization or may be limited to price optimization in the e-commerce setting do not make them any less abstract."). As a result, Appellant's preemption arguments are not persuasive.

In view of the foregoing, we determine claim 1 does not recite an inventive concept because claim 1 simply appends well-understood, routine, conventional activities previously known to the prescription, healthcare, and over-the-counter industry, specified at a high level of generality, to the abstract idea.

Summary

Therefore, under the USPTO's Revised Patent Eligibility Guidance, informed by our governing case law concerning 35 U.S.C. § 101, Appellant has not shown the Examiner erred in concluding claim 1 and claims 2–15 and 18–25 grouped therewith are directed to a judicial exception, i.e., an abstract idea, without significantly more, and thus, are patent-ineligible under § 101. In view of the foregoing, we sustain the Examiner's § 101 rejection of claims 1–15 and 18–25 as being directed to patent-ineligible subject matter.

Issue (2): Obviousness Under 35 U.S.C. § 103

With regard to the obviousness rejection, we have reviewed Appellant's arguments in the Briefs (Appeal Br. 23–33; Reply Br. 15–22),

the Examiner's rejection (Final Act. 7–21), and the Examiner's response (Ans. 13–14) to Appellant's arguments in the Appeal Brief.

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. *See In re Fine*, 837 F.2d 1071, 1073 (Fed. Cir. 1988). The Examiner's articulated reasoning in the rejection must possess a rational underpinning to support the legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). The USPTO "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks and citation omitted); *see Synopsys*, 814 F.3d at 1322 (stating that, as an administrative agency, the PTAB "must articulate logical and rational reasons for [its] decisions" (internal quotation marks and citation omitted)); *see also In re Nuvasive, Inc.*, 842 F.3d 1376, 1383 (Fed. Cir. 2016).

The claimed invention is not obvious if a person of ordinary skill would *not* select and combine the prior art references to reach the claimed invention. *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1379 (Fed. Cir. 2006) ("[T]o establish a prima facie case of obviousness based on a combination of elements in the prior art, the law requires a motivation to select the references and to combine them in the particular claimed manner to reach the claimed invention").

The determination of obviousness must consider, *inter alia*, whether a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and whether there would have

been a reasonable expectation of success in doing so. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1125 (Fed. Cir. 2000); *see also In re Rosuvastatin Calcium Pat. Litig.*, 703 F.3d 511, 517 (Fed. Cir. 2012); *Takeda Chem. Indus., Ltd. v. Alphapharm Pty.*, 492 F.3d 1350, 1361–62 (Fed. Cir. 2007). "[A] reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550–51 (Fed. Cir. 1983). Further, our reviewing court has held that "[a] reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *Ricoh Co. v. Quanta Computer, Inc.*, 550 F.3d 1325, 1332 (Fed. Cir. 2008) (quoting *Kahn*, 441 F.3d at 990); *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994); *see also Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1354 (Fed. Cir. 2012) (quoting *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (alterations omitted)) (A reference teaches away when it "'suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant.'").

In this light, in the instant case on appeal, we agree with Appellant that (i) paragraphs 16, 20 through 23, and 77 through 79 of Keravich (*see* Appeal Br. 25); and (ii) paragraphs 3 and 164 of Keravich (*see* Reply Br. 19–21), *discourage* interaction between a drug purchaser and a healthcare person at a point of sale as recited in the claims. In view of Keravich's teachings of a drug *vending machine* that "eliminate[s] the need for interaction between the

purchaser and a licensed practitioner" (Keravich ¶ 3; *see also* ¶¶ 16, 20–23, 164), "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *Ricoh*, 550 F.3d at 1332 (internal quotations omitted). Therefore, the Examiner has not (i) articulated a satisfactory explanation including a rational connection between the facts found and the choice made (*see Motor Vehicle Mfrs.*, 463 U.S. at 43), (ii) shown a reasonable expectation of success (*see Brown*, 229 F.3d at 1125), and/or (iii) articulated how any modification of Keravich would be productive of the result sought by Appellant's claims (*see W.L. Gore*, 721 F.2d at 1550–51).

Therefore, Appellant's main contention, that Keravich teaches away from the claimed invention (Appeal Br. 25–26; Reply Br. 17, 19–21), because Keravich seeks to avoid interaction of a healthcare person at a point of sale, whereas the recited invention requires the intervention of health care personnel, in the offering for sale of a drug (*see* Appeal Br. 25), is persuasive. Appellant's argument that Keravich "does not contemplate body fluids being obtained, e.g., at a point of sale – it merely contemplates biometric data **being inputted** by the purchaser" (*id.* at 25), and therefore, Keravich's disclosed self-service procedure teaches the *exact opposite* of the claimed invention which requires health care professional intervention (*see id.* at 26), is also persuasive. Keravich (*see* ¶¶ 3, 16, 20–23, 164) discourages against providing interaction with a healthcare person, as required by the claims (*see, e.g.*, claim 1, limitations [A], [C]), and, therefore, teaches away from Appellant's claimed invention. Keravich expressly teaches a drug "vending machine" (*id.* ¶¶ 3, 22, 23) that is for

avoiding any interaction with a healthcare person or licensed practitioner (*see id.* ¶¶ 3, 16, 20, 79, 164).

In view of the foregoing, we agree with Appellant's contentions that Keravich teaches away from the claimed invention (Appeal Br. 25–26; Reply Br. 17, 19–21), because Keravich seeks to *avoid* interaction of a healthcare person at a point of sale, whereas the recited invention requires the intervention of health care personnel, in the offering for sale of a drug (*see* Appeal Br. 25). Therefore, Appellant has shown the Examiner erred in rejecting representative claim 1, and thus, claims 2–15 and 18–25, under 35 U.S.C. § 103(a) because Keravich teaches away from the invention recited in claim 1.

As a result, based on the record before us, we cannot sustain the Examiner's obviousness rejection of independent claims 1 and 15, as well as claims 2–14 and 18–25 depending respectively therefrom, over the combination of Keravich and AAPA.

CONCLUSIONS

As explained above, Appellant has not shown the Examiner erred in rejecting claims 1–15 and 18–25 as being directed to patent-ineligible subject matter, and we sustain the rejection of claims 1–15 and 18–25 under 35 U.S.C. § 101. And, because Appellant has shown the Examiner erred in rejecting claims 1–15 and 18–25 over the combination of Keravich and AAPA, we do not sustain the Examiner's obviousness rejection of claims 1–15 and 18–25 over the combination of Keravich and AAPA.

Therefore, we affirm the Examiner's decision to reject claims 1–15 and 18–25, because at least one ground of rejection has been affirmed for

each claim. *See* 37 C.F.R. § 41.50(a)(1) ("The affirmance of the rejection of a claim on any of the grounds specified constitutes a general affirmance of the decision of the examiner on that claim, except as to any ground specifically reversed.").

DECISION SUMMARY

In summary:

Claims Rejected	**35 U.S.C. §**	**Reference(s)/Basis**	**Affirmed**	**Reversed**
1–15, 18–25	101	Eligibility	1–15, 18–25	
1–15, 18–25	103(a)	Keravich, AAPA		1–15, 18–25
Overall Outcome			1–15, 18–25	

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