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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte FRITZ F. PARL, PHILIP S. CROOKE, MARYLYN D. RITCHIE, DAVID L. HACHEY, SHEILA DAWLING, and NADY ROODI[1]

Appeal 2016-007791
Application 11/854,321
Technology Center 1600

Before ROBERT A. POLLOCK, TIMOTHY G. MAJORS, and RACHEL H. TOWNSEND, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants appeal under 35 U.S.C. § 134(a) from the non-final rejection of claims 1–24. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

STATEMENT OF THE CASE

Appellants' invention relates to a method of assessing breast cancer risk, which takes into account genotypic and phenotypic information relating to exposure to carcinogenic estrogen metabolites $4OHE_2$ and E_2-3,4-Q.

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[1] Appellants identify the Real Party in Interest as Vanderbilt University. App. Br. 1.

Spec. 5:3–22, Abstract. According to Appellants, the invention, as claimed, uses statistics to analyze subject data. App. Br. 2. The method thereby "determines that a subject has an increased risk of developing breast cancer if there is an increased production of 4-OHE_2 and/or E_2-3,4-Q produced by a determined allelic profile as compared to a mean population by the relevant genetic population." *Id.* Conversely, "[t]he subject is determined to have a decreased risk of developing breast cancer if there is a decreased population of 4-OHE_2 and/or E_2-3,4-Q produced by the determined allelic profile as compared to the mean population by the relevant genetic population." *Id.*

Claim 1 is representative (formatted):

> 1. A method for assessing a female subject's risk for developing breast cancer comprising:
>
> (a) determining, in a sample from said subject, the allelic profile of COMT, CYP1Al and CYP1B1;
>
> (b) predicting, based on an in silica model of estrogen biosynthesis, relative amounts of 4-OHE_2 and/or E_2-3,4-Q produced by the determined allelic profile;
>
> (c) comparing the relative amounts of 4-OHE_2 and/or E_2-3,4-Q produced by the determined allelic profile to a mean production amount of 4-OHE_2 and/or E_2-3,4-Q of a relevant genetic population;
>
> (d) determining that the subject has an increased risk of developing breast cancer if there is an increased production of 4-OHE_2 and/or E_2-3,4-Q produced by the determined allelic profile as compared to the mean production by a the [sic] relevant genetic population; and
>
> (e) determining that the subject has a decreased risk of developing breast cancer if there is a decreased production of 4-OHE_2 and/or E_2-3,4-Q produced by the determined allelic profile as compared to the mean production by a the [sic] relevant genetic population.

Depending from claim 1, claim 8 "further compris[es] assessing one or more aspects of the subject's personal history." Also depending from claim 1, claim 9 recites,

> wherein said one or more aspects are selected from the group consisting of age, ethnicity, reproductive history, menstruation history, use of oral contraceptives, body mass index, alcohol consumption history, smoking history, exercise history, diet, family history of breast cancer or other cancer including the age of the relative at the time of their cancer diagnosis, and a personal history of breast cancer, breast biopsy or DCIS, LCIS, or atypical hyperplasia.[2]

STATEMENT OF THE REJECTION

Claims 1–24 stand rejected under 35 U.S.C. § 101 as drawn to non-statutory subject matter.

35 U.S.C. § 101

We have reviewed Appellants' contentions that the Examiner erred in rejecting claims 1–24 as drawn to non-statutory subject matter under 35 U.S.C. § 101. App. Br. 9–14. We disagree with Appellants' contentions and adopt the Examiner's findings and well-reasoned conclusion. *See* Ans. 2–11. We provide the following comments for clarity and emphasis.

Section 101 of the Patent Statute broadly provides that, "[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

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[2] As Appellants do not address the subject matter of the dependent claims, they fall with claim 1. Nevertheless, in the event of further prosecution, we suggest that the Examiner consider whether there is sufficient antecedent support for all dependent claim elements.

title." Supreme Court precedents, however, provide three specific exceptions to the broad categories of eligible subject matter under § 101: laws of nature, natural phenomena, and abstract ideas. *Bilski v. Kappos*, 561 U.S. 593, 625 (2010). "The 'abstract ideas' category embodies 'the longstanding rule that '[a]n idea of itself is not patentable."' *Alice Corp. Pty. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014) (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)). In *Alice*, the Supreme Court referred to the two-step analysis set forth in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), as providing "a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Alice*, 134 S. Ct. at 2355 (citing *Mayo*, 132 S. Ct. at 1289). Under *Alice*, "[w]e must first determine whether the claims at issue are directed to a patent-ineligible concept." *Id.* Next, "we consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* (citing *Mayo*, 132 S. Ct. at 1297–98).

To be patentable under *Mayo*, a claim must do more than simply state the law of nature or abstract idea and add the words "'apply it."' *Mayo*, 132 S. Ct. at 1294; *Benson*, 409 U.S. at 67. Likewise, "[s]imply appending conventional steps, specified at a high level of generality," is not "enough" for patent eligibility. *Alice*, 134 S. Ct. at 2357 (quoting *Mayo*, 132 S. Ct. at 1300). Moreover, "[w]hile preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility. . . . Where a patent's claims are deemed only to disclose patent

ineligible subject matter under the *Mayo* framework, . . . preemption concerns are fully addressed and made moot." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015), *cert. denied*, No. 15-1182, 2016 WL 1117246 (U.S. June 27, 2016); *see also Vehicle Intelligence & Safety LLC v. Mercedes-Benz USA, LLC*, 635 F. App'x 914, 918 (Fed. Cir. 2015), *cert. denied*, No. 15-1201, 2016 WL 1171121 (U.S. May 31, 2016) ("And while assessing the preemptive effect of a claim helps to inform the *Mayo/Alice* two-step analysis, the mere existence of a non-preempted use of an abstract idea does not prove that a claim is drawn to patent-eligible subject matter.").

With respect to step one of the *Mayo/Alice* analysis, Appellants argue that the claims "are not nature-based" because "predicting an individual subject's future risk for a serious disease . . . represents a practical application of the research on which it is based." App. Br. 12. We do not find that argument persuasive.

First, the claims regarding assessing a subject's risk of developing a disease at issue here are similar to the multistep claims of assessing a subject's risk of disease or developing a complication of a particular disease found to be directed to a law of nature in *Cleveland Clinic v. True Health Diagnostics LLC*, 859 F.3d 1352 (Fed. Cir. 2017). In that case, the Federal Circuit noted that

> the testing patent [claims] purport to detect MPO and other MPO-related products, which are naturally occurring in bodily samples. The [claimed] method then employs the natural relationship between those MPO values and predetermined or control values to predict a patient's risk of developing or having cardiovascular disease.

Cleveland Clinic, 859 F.3d at 1361. The Court further noted that those claims are directed to a natural law because they

> start[] and end[] with naturally occurring phenomena with no meaningful non-routine steps in between—the presence of MPO in a bodily sample is correlated to its relationship to cardiovascular disease.

Id.

Furthermore, we note that just because an invention "effectuate[s] a practical result and benefit not previously attained," does not immunize it from invalidity under § 101 of the Patent Statute. *Ariosa*, 788 F.3d at 1381 (J. Reyna concurring) (citation omitted); *see also Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1315 (Fed. Cir. 2016) ("'[t]he 'novelty' of any element or steps in a process, or even of the process itself, is of *no relevance* in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.' *Diamond v. Diehr*, 450 U.S. 175, 188–89 (1981) (emphasis added); *see also Mayo*, 132 S.Ct. at 1303–04 (rejecting 'the Government's invitation to substitute §§ 102, 103, and 112 inquiries for the better established inquiry under § 101')").

We are compelled to agree with the Examiner that the claims on appeal are drawn to a natural phenomenon or law of nature, in particular, a relationship between genotypic information relating to a subject's estrogen-metabolizing enzymes (COMT, CYP1Al and CYP1B1), and the likelihood that she has an increased or decreased risk for breast cancer as compared to a relevant population. *See* Ans. 2–3. This naturally occurring relationship exists apart from any human action, regardless of the statistical model used to manipulate the data and correlate the genotypic information with a risk

assessment. In short, the claims at issue focus on a fact of human biology, involve no creation or alteration of the genotype or phenotype of the subject, and do not purport to identify novel detection techniques. *See, e.g., Genetic Techs. Ltd. v. Merial LLC*, 818 F.3d 1369, 1376 (Fed. Cir. 2016) (concluding that a method directed to detecting a coding allele was directed to a patent-ineligible law of nature because it "focuses on a newly discovered fact about human biology (the linkage of coding and non-coding regions of DNA), involves no creation or alteration of DNA sequences, and does not purport to identify novel detection techniques"). Moreover, steps of collecting and analyzing information by steps people go through in their minds, or by mathematical algorithms, such as are involved in the claims at issue here, without more, are "mental processes within the abstract-idea category." *FairWarning IP, LLC v. Iatric Sys., Inc.*, 839 F.3d 1089, 1093 (Fed. Cir. 2016).

With respect to step 2 of the *Mayo/Alice* framework, Appellants argue that "the active method steps of the claims are not known in the art," yet admit that the Examiner "had previously cited Mitrunen et al. and Yager et al, as disclosing measuring CYP1A1, CYPlB1 and COMT polymorphisms," as well as "Hanna et al., Ritchie et al., and Dawling et al., as disclosing measurements of enzymatic activity of allelic variants of CYP1A1, CYP1B1 and COMT proteins." App. Br. 13–14; *see also* Ans. 5 (citing references). Appellants further argue that

> the mere knowledge in the art of the existence of enzymatic activity of CYP1A1, CYP1B1 and/or COMT allelic variants does not establish that it was conventional for scientists in the field of the present invention(s) to evaluate the specifically claimed allelic profile of COMT, CYP1A1 and CYP1B1 in the context of the claimed method(s) to assess a subject's risk for

> developing breast cancer and/or for determining the need for routine diagnostic testing of a female subject for breast cancer.

Id. at 14.

We do not find Appellants' arguments persuasive. We are, instead, satisfied that the Examiner correctly considered the claim elements both individually and as an ordered combination to determine whether they transform the nature of the claim into a patent-eligible application. *See* Ans. 5–7, 9–10. As noted by the Examiner, "[t]he active method step of claim 1, 'determining in a sample from a subject, the allelic profile of COMPT, CYP1A1 and CYP1B1' is recited at a high level of generality such that substantially all practical applications are covered. In addition, the step relies on well-understood, routine and conventional methods." Ans. 5.

> In addition, the method steps for determining in a sample from a subject, the allelic profile of COMPT, CYP1A1 and CYP1 B1 such as amplifying nucleic acid from the sample by PCR on a chip are conventional well understood routine methods for determining allelic profiles. These steps are the activities that a scientist would have relied upon to achieve the goals of the invention. Thus, in the present case, the active method steps set forth well-understood routine and conventional activity engaged in by scientists and are the activities that a scientist would have relied upon to determine the allelic profiles of COMPT, CYP1A1 and CYP1B1.

Id. at 6. Considering the claims as a whole, the individual steps fail to provide significantly more than the judicial exception itself. *See id.* at 7; *see also Mayo* 132 S. Ct. 1289, 1298 ("[T]he 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."). In sum, the

claims before us merely inform the relevant audience of certain laws of nature: specifically, the relationship between a patient's allelic profile and the patient's risk of developing breast cancer. *See Cleveland Clinic*, 859 F.3d at 1362 (concluding that claims of a method that relate the natural phenomena of MPO being associated with cardiovascular risk are not directed to a patentable invention because the process steps of detecting/determining MPO levels and comparing the levels to statistically derived control or predetermined values, whether considered limitation-by-limitation or as a whole "merely tell those 'interested in the subject about the correlations that the researchers discovered.' Mayo, 566 U.S. at 78"); *see also Genetic Techs.*, 818 F.3d at 1379–80 (finding claims unpatentable under § 101 where, "the novelty of looking to non-coding DNA to detect a coding region allele of interest resides in the novelty of the newly discovered natural law of linkage disequilibrium between coding and non-coding regions and adds little more than a restatement of the natural law itself.").

Appellants also argue that, "when viewed as a whole, the claims do not seek to tie up any judicial exception such that others cannot practice it." App. Br. 11. We do not find Appellants' arguments persuasive. "[T]he absence of complete preemption does not demonstrate patent eligibility." *Ariosa*, 788 F.3d at 1379. "Where a patent's claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework, as they are in this case, preemption concerns are fully addressed and made moot." *Id.*

For the above reasons, and those set forth in the Examiner's Answer, we sustain the rejection.

SUMMARY

We *affirm* the rejection of claims 1–24 under 35 U.S.C. § 101 as drawn to non-statutory subject matter.

TIME PERIOD FOR RESPONSE

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

AFFIRMED