UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/451,210	04/19/2012	Andrei Manolescu	30847/44317A	4204

4743 7590 11/18/2016

MARSHALL, GERSTEIN & BORUN LLP
233 SOUTH WACKER DRIVE
6300 WILLIS TOWER
CHICAGO, IL 60606-6357

EXAMINER
HANEY, AMANDA MARIE

ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
11/18/2016	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mgbdocket@marshallip.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ANDREI MANOLESCU,
ANNA HELGADOTTIR, and
GUDMAR THORLEIFSSON[1]

Appeal 2014-000655
Application 13/451,210
Technology Center 1600

Before ULRIKE W. JENKS, ROBERT A. POLLOCK, and
TAWEN CHANG, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants appeal under 35 U.S.C. § 134(a) from the final rejection of claims 1–20 and 22–31. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

---

[1] Appellants identify the Real Party in Interest as assignee deCODE genetics ehf, located in Reykjavik Iceland. Appellants further state that deCODE is a subsidiary of Amgen, Inc. App. Br. 3.

STATEMENT OF THE CASE

Appellants' invention relates to "methods of diagnosing susceptibility to cardiovascular disease, including coronary artery disease, MI [(myocardial infarction)], abdominal aorta aneurysm, intracranial aneurysm restenosis and peripheral arterial disease, by assessing the presence or absence of alleles of certain polymorphic markers found to be associated with cardiovascular disease." Spec. Abstract.

Claims 1, 22, and 27 are independent. Claim 1 is illustrative (additional paragraphing added):

> 1. A method for determining a susceptibility to arterial disease in a human individual, comprising
>
> determining the presence or absence of allele G of polymorphic marker rs10757278 in a nucleic acid sample from the individual, and
>
> determining an increased susceptibility to arterial disease for the human individual from the presence of the G allele of rs10757278 in the nucleic acid sample, or
>
> determining a decreased susceptibility to arterial disease from the absence of the G allele of rs10757278 in the nucleic acid sample.

Claims 1–20 and 22–31 stand rejected for obviousness-type double patenting in view of claims 1, 4–8, 10–11, 23, 34–37, 47–51, 66, 75, 83 of copending application No. 12/302,538 and, with respect to claim 31, further in view Stephan.[2] Final Rejection ("Fin. Rej.") dated Jan. 29, 2013, 13–18; Advisory Action dated April 23, 2013, 2; Examiner's Answer ("Ans.") dated Aug. 14, 2013, 12.

---

[2] Stephan et al. US 2008/0131887 (A1), published June 5, 2008.

Claims 1–20 and 22–31 stand rejected as drawn to non-patentable subject matter under 35 U.S.C. § 101.

ANALYSIS

Obviousness-type Double Patenting

Appellants decline to address the merits of the Examiner's rejections of claims 1–20 and 22–31 for obviousness-type double patenting. *See* App. Br. 12. We summarily affirm the rejection. *See* MPEP § 1205.02 ("If a ground of rejection stated by the examiner is not addressed in the appellant's brief, appellant has waived any challenge to that ground of rejection and the Board may summarily sustain it."); *Ex parte Frye*, 94 USPQ2d 1072, 1075 (BPAI 2010) (precedential) ("If an appellant fails to present arguments on a particular issue – or, more broadly, on a particular rejection – the Board will not, as a general matter, unilaterally review those uncontested aspects of the rejection.").

35 U.S.C. § 101

We have considered Appellants' contentions that the Examiner erred in rejecting claims 1–20 and 22–31 as drawn to unpatentable subject matter. App. Br. 12–50; Reply Br. 3–24; *see* Transcript of Oral Hearing dated Oct. 4, 2016. We disagree with Appellants' contentions and adopt as our own the Examiner's factual findings and legal conclusions. Fin. Rej. 2–13; Advisory Action 2; Ans. 2–15. We provide the following additional 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 title." Supreme Court precedents, however, provide three specific exceptions to the broad categories of § 101: laws of nature, natural phenomena, and abstract ideas. *Bilski v. Kappos*, 561 U.S. at 625. "The 'abstract ideas' category embodies the longstanding rule that '[a]n idea of itself is not patentable.'" *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014) (citing *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 Servs. v. Prometheus Labs., 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 *Mayo*, "[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, as they are in this case, 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.").

To summarize the Examiner's position, the claims on appeal are "drawn to methods for determining/diagnosing/assessing susceptibility to arterial disease," which require determining the presence of a polymorphic marker (the G allele of rs10757278) and correlating the presence or absence of this marker with susceptibility to arterial disease. *See* Fin. Rej. 3. According to the Examiner, this correlation between the G allele of rs10757278 and susceptibility to arterial disease is a law of nature. *Id.* In accord with step 2 of the *Alice/Mayo* framework, the Examiner further determined that any additional claim steps "consist of well-understood, routine, conventional activity already engaged in by the scientific community" which, "when viewed as a whole, add nothing significant beyond the sum of their parts taken separately." *Id.*

Appellants contend, *inter alia*, that the Examiner's rejection is improper because "even if . . . the present invention involves a 'law of nature,' the claims are not directed to the law of nature per se, but to a

practical application of it." App. Br. 13 (emphases removed). We do not find Appellants' argument persuasive.

The appealed claims are generally drawn to determining an increased (or decreased) susceptibility to arterial disease based on the presence (or absence) of a particular polymorphic allele. This is precisely on point with the claims found unpatentable in *Mayo*, which "set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." *Mayo*, 132 S. Ct. at 1296. The claims before us similarly inform the relevant audience of certain laws of nature: specifically, the relationship between the G allele of rs10757278 in an individual's genome and susceptibility to heart disease. *See also Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1379–80 (Fed. Cir. 2016), *cert. denied*, (U.S. Oct. 3, 2016) (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 appear to contend that, unlike the claims at issue in *Mayo*, the claims before us recite the practical application of advising individuals of their risk of heart disease. *See e.g.,* App. Br. 21 ("The claimed invention informs a subject about the subject's susceptibility to arterial disease, not about a law of nature."); *id.* at 27 ("[T]he claims constitute a *practical application:* a prognostic test for a human individual that identifies the presence or absence of a heightened risk of disease."); Tr. 7:6–8:10 ("Advising a risk is a practical application.").

None of the claims before us, with the possible exception of claim 7, discussed below, recites a step of advising individuals of their risk of heart disease. *McRO* and *CellzDirect*, raised by Appellants at oral argument are, therefore, inapposite at least with respect to those claims. *See* Tr. 3:10–14, 5:2–6:7 (referencing *McRO, Inc. v. Bandai Namco Games Am. Inc.,* No. 2015-1080, 2016 WL 4896481 (Fed. Cir. Sept. 13, 2016); *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016)).

In contrast to the claims on appeal, those at issue in *McRO* expressly recite an application step, namely, "applying said final stream of output morph weight sets to a sequence of animated characters to produce lip synchronization and facial expression control of said animated characters." WL 4896481 at *3. The court determined that McRO's claims are not directed to an unpatentable abstract idea, but instead are directed to "a specific asserted improvement in computer animation." *Id.* at 8. In particular, the court explained that claimed process as a whole, "renders information into a specific format that is then used and applied to create desired results: a sequence of synchronized, animated characters." *Id.* at 9.

The representative claim in *Cellzdirect* also recites an express application step, in this case involving, "cryopreserving [] recovered viable hepatocytes." 827 F.3d at 1046. The court found the claim "patent eligible because it applies the discovery that hepatocytes can be twice frozen to achieve a new and useful preservation process." *Id.* at 1050–1051. The claims before us, however, merely inform the relevant audience of the existence of a correlation between one allele of a polymorphic locus and susceptibility to arterial disease, without reciting a practical application of that relationship.

We further note that dependent claim 7 recites the step of "communicating the susceptibility to at least one entity selected from the group consisting of the individual, a genetic counselor, a physician, and a healthcare worker." Merely presenting the results of a process otherwise unpatentable under section 101 is, however, insufficient to establish eligibility under the statute. *See FairWarning IP, LLC v. Iatric Sys., Inc.*, No. 2015-1985, 2016 WL 5899185, at *3 (Fed. Cir. Oct. 11, 2016) (claim unpatentable under § 101 despite recitation of the step: "providing notification if [an] event has occurred").

To the extent that a step of advising individuals of their risk of heart disease may be somehow implicit in the claims on appeal, they would not differ substantially from those found invalid in *Mayo*. The claims at issue in *Mayo* include a step of determining the level of a 6-thioguanine metabolite in a patient, and "wherein" clauses indicating a need to increase (or decrease) the amount of parent drug subsequently administered when the patient's 6-thioguanine levels were less than (or greater than) specified limits. *Mayo*, 132 S. Ct. at 1295 (e.g., a "level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject"). The "wherein" clauses thus describe metabolite concentrations above which there is a likelihood of harmful side-effects and below which it is likely that the drug dosage is ineffective, thereby informing doctors that metabolite concentrations above or below these thresholds "indicate a need" to adjust the drug dosage. *See id.* at 1295. The Court explained that these limitations

> simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient. That is to say, these

> clauses tell the relevant audience about the laws while trusting them to use those laws appropriately where they are relevant to their decisionmaking (rather like Einstein telling linear accelerator operators about his basic law and then trusting them to use it where relevant).

Id. at 1297.

Thus, once the relationship between safe and effective dosing of the parent drug and threshold levels of the 6-thioguanine metabolite was known, the claims at issue in *Mayo implicitly* direct a health care provider to increase (or decrease) the amount of drug administered when metabolite levels are below (or above) certain thresholds. *See also Genetic Techs.*, 818 F.3d at 1379 (claim step of "analyzing the amplified DNA sequence to detect the allele" "merely informs the relevant audience—e.g., doctors or others seeking to make a genetic diagnosis—to apply a law of nature for a purpose—detecting a polymorphism within a coding region of an allele of interest). Accordingly, to the extent the claims on appeal may be read to *implicitly* include the step of advising patients of their risk of heart disease, we remain constrained to find them unpatentable for the same reasons as those at issue in *Mayo*.

SUMMARY

I. We *summarily affirm* the rejection of claims 1–20 and 22–31 for obviousness-type double patenting.

II. We *affirm* the rejection of claims 1–20 and 22–31 under 35 U.S.C. § 101 as drawn to non-patentable 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