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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MARIANNE TUEFFERD, JÉRÔME DAUVILLIER, ARNAUD DELAYE, and SONIA SCHNIEPER-SAMEC[1]

Appeal 2014-005639
Application 13/131,131
Technology Center 1600

Before JEFFREY N. FREDMAN, RICHARD J. SMITH, and RYAN H. FLAX, *Administrative Patent Judges*.

SMITH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method for treating Growth Hormone Deficiency (GHD). We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

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[1] According to Appellants, the real party in interest is Merck Serono SA. (Br. 3.)

STATEMENT OF THE CASE

Background

"[T]he present invention relates . . . to genetic markers associated with the clinical response to Growth Hormone in Growth Hormone Deficiency (GHD) . . . . The invention further discloses specific polymorphisms or alleles of several genes that are related to GHD." (Spec. 1, ll. 6–12.)

Claims on Appeal

Claims 50, 52, and 56–59 are on appeal. (Claims Appendix, Br. 9–10.) Independent claim 50 is illustrative and reads as follows:

50. A method for treating Growth Hormone Deficiency (GHD) in an individual comprising identifying the level of response to treatment with growth hormone (GH) by an individual, said identifying comprising:

(a)(i) obtaining a DNA sample of said individual; and

(a)(ii) determining whether in PTPN1 – rs941798 the AA genotype is present, the presence of the AA genotype identifying the individual as a low responder to GH treatment; or

(b)(i) obtaining a DNA sample of said individual;

(b)(ii) determining whether in PTPN1 – rs941798 the AA genotype and/or in CDK4 – rs2270777 the GG or GA genotype is present, the presence of the AA genotype in PTPN1 – rs941798 or the presence of the GG or GA genotype in CDK4 – rs2270777 the identifying the individual as a low responder to GH treatment; and

treating an individual identified as a low responder to GH treatment with a long-acting analogue of GH or with a dose of growth hormone that is increased compared to the standard dose.

Examiner's Rejection

Claims 50, 52, and 56–59 stand rejected under 35 U.S.C. § 101 as directed to non-statutory subject matter; namely, as claiming a law of nature. (Ans. 2.)

Appellants argue claims 50, 52, and 56–59 as a group, and we therefore limit our discussion to claim 50.

ISSUE

Whether a preponderance of evidence of record supports the Examiner's conclusion that claim 50 is directed to non-statutory subject matter.

ANALYSIS

We adopt as our own the findings and reasons set forth by the Examiner in (1) the action from which this appeal is taken (Final Act. 3–7) and (2) the Examiner's Answer in response to Appellants' Appeal Brief (Ans. 2–11), and concur with the conclusions reached by the Examiner. Moreover, we agree with the Examiner that claim 50 sets forth a patent-ineligible law of nature; specifically, the correlation between particular alleles and response to GH treatment. (Ans. 4.) We highlight the following for emphasis.

We follow, as did the Examiner, the analytical framework set forth by the Supreme Court in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.,*132 S.Ct. 1289 (2012). Moreover, similar to the claims found patent-ineligible in *Mayo*, claim 50 is directed to a method for optimizing treatment by adjusting administration of a therapeutic agent based on a law of nature. *See id.* at 1295–96. In addition, just as in *Mayo*, claim 50 "inform[s] 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." *See id.* at 1298.

CONCLUSION

A preponderance of evidence of record supports the Examiner's conclusion that claim 50 is directed to non-statutory subject matter. Claims 52 and 56–59 were not argued separately and fall with claim 50.

SUMMARY

We affirm the rejection of all claims on appeal.

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