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THE PROCTER & GAMBLE COMPANY
GLOBAL IP SERVICES
CENTRAL BUILDING, C9
ONE PROCTER AND GAMBLE PLAZA
CINCINNATI, OH 45202

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MAKIO TAMURA, ROSEMARIE OSBORNE, and
HEATHER LYNN ROCCHETTA

Appeal 2018-005659
Application 14/851,418
Technology Center 1600

Before RICHARD M. LEOVITZ, RACHEL H. TOWNSEND, and
CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

HARDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner's decision to reject claims 30 and 33. *See* Final Act. 4. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

¹ We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as The Procter & Gamble Company. Appeal Br. 1.

CLAIMED SUBJECT MATTER

The claims are directed to a method for identifying an agent effective for transcriptionally up-regulating an eigengene associated with a desirable cosmetic phenotype of human skin. Claim 30, reproduced below (with spacing added for ease of reading), is illustrative of the claimed subject matter:

30. A method for identifying an agent effective for transcriptionally up-regulating an eigengene associated with a desirable cosmetic phenotype of human skin, the method comprising:

deriving an eigengene for a co-expression module determined from a set of genes transcriptionally up-regulated in human skin exhibiting the desirable cosmetic phenotype and a set of genes associated with a clean and detox biological theme selected from the group consisting of protein catabolic process, regulation of autophagy, regulation of endopeptidase activity, and regulation of proteolysis;

treating skin with a putative agent;

conducting a transcriptional assessment of the eigengene in the treated skin; and

identifying the putative agent as an effective clean and detox agent if the eigengene is up-regulated in the treated skin.

Appeal Br. 6 (Claims Appendix).

REFERENCE

The prior art relied upon by the Examiner is:

Name	Reference	Date
Giuliani	US 2014/0163118 A1	June 12, 2014

REJECTIONS

Claims 30 and 33 stand finally rejected by the Examiner under 35 U.S.C. § 102(a)(1) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over, Giuliani. Final Act. 4.

OPINION

“[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability.” *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). We determine that the Examiner has not carried the burden of presenting a *prima facie* case of unpatentability.

“Anticipation requires that all of the claim elements and their limitations are shown in a single prior art reference.” *In re Skvorecz*, 580 F.3d 1262, 1266 (Fed. Cir. 2009). In relevant part, independent claim 30 recites “deriving an eigengene” from two sets of genes, one of which is “a set of genes associated with a clean and detox biological theme selected from the group consisting of protein catabolic process, regulation of autophagy, regulation of endopeptidase activity, and regulation of proteolysis.” Appeal Br. 6 (Claims Appendix). The Specification teaches that

[u]nder the Eigengene model, a “module” is a group of interconnected genes that forms a biological pathway, process or theme, and an intersecting set of two or more modules is called a “co-expression module.” A gene expression profile of a module or co-expression module may be represented by an “eigengene,” and eigengene networks may be constructed to represent the relationships between and within genetic co-expression modules. Derivation of an “eigengene” collapses many data points into a single vector. An eigengene may be thought of as a summary of a module expression profile into a single representative gene. An eigengene reflects the variance between the genes comprising the modules.

Spec. 3:23–30. The Examiner found that Giuliani teaches the “deriving an eigengene” limitation via its disclosure of “gene expression signature of

genes and coordinately expressed gene networks associated with skin aging.” Final Act. 4 (citing Giuliani Abstract).

Appellant acknowledges that Giuliani teaches connected networks of genes involved in skin aging, but argues that Giuliani does not teach “‘deriving an eigengene’ from the connected networks.” Appeal Br. 2–3. Appellant argues that “[a]t most, the disclosure in Giuliani [sic] might be construed as recognizing that co-expression modules exist. But Giuliani does not teach summarizing co-expression modules profiles into a single representative gene, i.e., an eigengene.” *Id.* at 3; *see also* Reply Br. 3 (arguing that in Giuliani, there is “no disclosure of summarizing such a higher order organization of interconnected networks into a single vector”).

On this record, we determine that in general, Giuliani teaches derivation of eigengenes. For example, Giuliani teaches that “skin aging results from the dysregulation of **key regulatory genes (i.e., gene signatures) that control thousands of genes** in multiple, interacting and overlapping networks and pathways.” Giuliani ¶ 4 (emphasis added). Giuliani also teaches a method that includes the steps of identifying genes, networks, and pathways associated with skin aging, and identifying a “**small number of genes whose expression can serve as predictors** (i.e. biomarkers) of skin aging.” Giuliani ¶ 69 (emphasis added). Giuliani also teaches that “[k]ey to this and future work is the **identification of nodes (genes) that connect networks together**. It is the **gene signatures** in different but connected and interacting networks that determine the aging process.” Giuliani ¶ 66 (emphasis added). Based on the current record, Giuliani’s “key regulatory genes (i.e., gene signatures)” and “small number of genes whose expression can serve as predictors (i.e. biomarkers of skin

aging)”) appear to be akin to Appellant’s eigengene, which, again, is described in the Specification as “a summary of a module expression profile into a single representative gene.” Spec. 3:28–29.

Nevertheless, we determine that the Examiner has not demonstrated a *prima facie* case of anticipation. As noted above, independent claim 30 requires that the eigengene be derived from two specific sets of genes, one of which is “a set of genes associated with a clean and detox biological theme selected from the group consisting of protein catabolic process, regulation of autophagy, regulation of endopeptidase activity, and regulation of proteolysis.” The Examiner has not demonstrated that Giuliani teaches any genes that fall within this recited set. As such, the Examiner has not demonstrated that Giuliani teaches all of the limitations of claim 30. Claim 33 depends from claim 30, and thus also requires presence of this limitation in the prior art to support a finding of anticipation.

The Examiner asserts that “deriving an eigengene . . . determined from a set of genes” is “a mental step, wherein the user determines what would be considered ‘clean and detox’ selected from ‘protein catabolic process . . . ,” and that “[i]t does not matter if this deriving/determining mental step of the user is proven wrong or right by other scientists.” *Id.* Final Act. 5. We are not persuaded by the Examiner’s arguments.

First, we agree with Appellant that the Examiner has not “provided any evidence or reasoning beyond the conclusory statement in the Final Rejection to show that these limitations could be performed entirely in the human mind.” Appeal Br. 3. Appellant points to Example 2 in the Specification, where an eigengene was derived via “[s]ingular value decomposition [] applied to the transcriptome profile” for co-expression

modules for a “‘younger-appearance’ gene set and each of several biological process/theme modules.” Appeal Br. 3 (quoting Spec. 19:27–20:2). The Examiner has not explained how such steps could be performed in the human mind. More importantly, however, even if the step of deriving the eigengene step could be performed in the mind, that does not excuse the Examiner from having to demonstrate that Giuliani teaches “a set of genes associated with a clean and detox biological theme” selected from the recited group in order to support a finding of anticipation, and the claim still requires “conducting a transcriptional assessment of the eigengene in the treated skin.” See, e.g., *Metabolite Labs Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367 (Fed. Cir. 2004) (prior art did not anticipate because it failed to teach, among other limitations, the claimed “correlating” step).

With respect to the alternative obviousness rejection, the Examiner addresses only claim 33, stating that this claim “appears to be repeating the same active steps, but using different deriving/determined mental steps,” and that “[i]t would have been obvious for one skilled in the art to repeat the same active steps to determine other genes associated in the aging process and determining where [sic] wrong or right what those genes might do in skin aging.” Final Act. 5. This analysis is deficient for the same reason discussed above, i.e., that the Examiner has not demonstrated that Giuliani teaches deriving an eigengene in part from “a set of genes associated with a clean and detox biological theme” selected from the recited group, as required by independent claim 30.

The Examiner does not provide a reasoned explanation for the obviousness rejection of claim 30. In an *ex parte* appeal, the Board “is basically a board of review—we review final rejections made by patent

examiners. In order to have meaningful review, we must be able to understand the examiner’s rejection” *Ex parte Gambogi*, 62 USPQ2d 1209, 1211–12 (BPAI 2001). Because the Examiner has not detailed any differences between claim 30 and Giuliani, or any reasons why a person of ordinary skill in the art would have concluded that the invention defined by the limitations of claim 30 would have been an obvious variation of what is disclosed in Giuliani, we are constrained to reverse the obviousness rejection of claim 30.

For the reasons discussed above, we determine that the Examiner has not established a *prima facie* case of unpatentability of claims 30 and 33 based on anticipation or obviousness over Giuliani.

CONCLUSION

We reverse the rejection of claims 30 and 33 under 35 U.S.C. § 102(a)(1) as anticipated by Giuliani.

We reverse the rejection of claims 30 and 33 under 35 U.S.C. § 103 as obvious over Giuliani.

DECISION SUMMARY

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
30, 33	102(a)(1)	Giuliani		30, 33
30, 33	103	Giuliani		30, 33
Overall Outcome:				30, 33

REVERSED