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THE PROCTER & GAMBLE COMPANY  
Global IP Services  
Central Building, C9  
One Procter and Gamble Plaza  
CINCINNATI, OH 45202

EXAMINER
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* ROBERT LLOYD BINDER, ROBERT SCOTT YOUNGQUIST,  
JUN XU, KENTON DUANE JUHLIN, ROSEMARIE OSBORNE, and  
SCOTT MICHAEL HARTMAN

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Appeal 2017-008235  
Application 14/749,779  
Technology Center 1600

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Before DEMETRA J. MILLS, FRANCISCO C. PRATS, and  
ULRIKE W. JENKS, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant<sup>1</sup> appeals from Examiner's decision to reject claims as being indefinite, lacking written descriptive support, and for being directed to non-statutory subject matter. We have jurisdiction under 35 U.S.C. § 6(b). We REVERSE.

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<sup>1</sup> The Appeal Brief ("Br.") lists The Procter & Gamble Company of Cincinnati, Ohio, the assignee of record, as the real party in interest. Br. 1. We have considered, and herein refer to, the Specification of June 25, 2015 ("Spec."); Final Office Action of Aug. 26, 2016 ("Final Act."); Appeal Brief of Jan. 30, 2017 ("Appeal Br."); Examiner's Answer of Mar. 17, 2017 ("Ans."); and Reply Brief of May 11, 2017 ("Reply Br.").

STATEMENT OF THE CASE

Claims 1 and 7–18 are on appeal, and can be found in the Claims Appendix of the Appeal Brief. Claim 1 is representative of the claims on appeal, and reads as follows:

1. A method of making a skin care composition, comprising:

(a) accessing a computer readable medium having stored thereon a plurality of instances and at least one skin aging gene expression signature, wherein each instance is associated with a cosmetic agent and wherein each instance comprises an ordered list of identifiers representing a plurality of up-regulated and a plurality of down regulated genes differentially expressed in response to contact between the cosmetic agent and a human dermal fibroblast cell or a human keratinocyte cell, the skin aging gene expression signature comprises one or more lists comprising a plurality of identifiers representing a plurality of up-regulated genes and a plurality of down-regulated genes associated with a skin aging condition, and from about 80% to about 100% of the plurality of identifiers associated with the skin aging gene expression signature represent a gene set forth in any of Tables A to D;

(b) comparing the skin aging gene expression signature to each of the instances, wherein the comparison comprises comparing each identifier in the gene expression signature list(s) with the position of the same identifier in the ordered lists for each of the instances;

(c) assigning a connectivity score to each instance based on the comparison in (b);

(d) generating a list of cosmetic agents associated with each instance that has a negative connectivity score; and

(e) incorporating at least one of the cosmetic agents from the list in (d) into a skin care composition; and

wherein at least one of steps (a), (b), (c) and (d) are performed by a programmable computing device comprising computer-readable instructions for executing the at least one step.

Appeal Br. 14–15 (Claims Appendix).

Appellant requests review of following rejections made by Examiner:

- I. Claims 1 and 7–18 under 35 U.S.C. § 112, second paragraph as being unclear what the standard is to calculate the connectivity score.
- II. Claims 1 and 7–18 under 35 U.S.C. § 112, first paragraph as failing to sufficiently describe the structure/function relationship to encompass the genus of cosmetic agents now claimed.
- III. Claims 1 and 7–18 under 35 U.S.C. § 101, as being directed to an abstract idea.

I. *Indefiniteness*

Examiner found that the term “negative connectivity score” as recited in claim 1 step (d) is indefinite because “[i]t is unclear what standard of reference is contemplated for evaluating whether connectivity score has a ‘negative correlation.’” Ans. 2. Specifically, Examiner explains “that because none of [steps] (a)-(c) of claim 1 clearly define what is used as a standard of comparison, the steps to be carried out in (d) and (e) are unclear.” *Id.* at 8. Examiner further explains that “the claim fails to set forth specific method steps that would allow a ‘connectivity score’ to be calculated as set forth in the specification, and thus an artisan would not know how to practice the method as claimed.” *Id.* at 9.

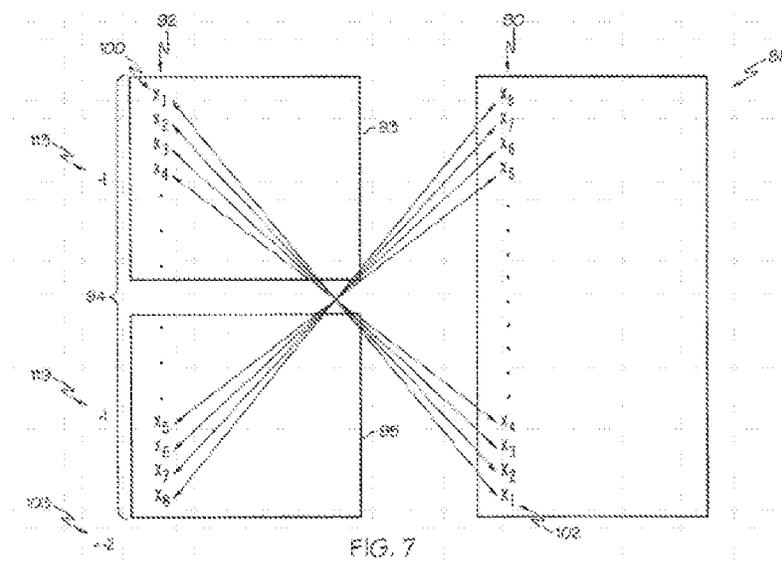
Appellant contends that the claim does not recite “negative correlation” and that the Specification “discloses that negative connectivity occurs when the up-regulated genes of a gene expression signature are predominately found among the down-regulated genes of an instance, and vice-versa.” Appeal. Br. 3 (citing Spec. 34:29–35:17, Fig. 6, and Fig. 7), *see* Reply Br. 1–2.

We are not persuaded by Examiner's contention that an artisan would not know how to practice the invention as claimed. We agree with Appellant that the Specification provides sufficient guidance on how to determine a connectivity score for a particular gene and to be able to determine if the gene shows a negative connectivity when compared to a gene expression signature. A "connectivity score" as recited in the Specification "refers to a derived value representing the degree to which an instance<sup>2</sup> correlates to a query." Spec. 19:14–15. Example 1 of the Specification, explains how each gene expression profile for each instance is generated. *See* Spec. 43–44. Tables A–D disclose skin aging gene expression signatures. *See* Spec. 44–49. To obtain the connectivity score requires comparing each identifier result of an instance with the results of the same identifier in one of the skin aging gene expression signatures set out in Tables A–D. *See* Spec. 50–64, Fig. 6–8. The Specification explains that those instances that have a negative connectivity score "are predicted to have [a] beneficial effect" because they are counter acting the activity associated with photo-aging or intrinsic aging. *See* Spec. 51:1–3, 65, Fig. 6–8. "Since both intrinsic aging and photo-aging are considered adverse conditions, it is preferential to find materials that tend to reverse one or both of the gene expression signatures. Such materials will have negative connectivity score, and the more negative the score the stronger the negative connection." Spec. 65:4–7.

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<sup>2</sup> The Specification defines an instance: as data from a gene expression profiling experiment in which skin cells are exposed to a perturbation. Spec. 16:22–23.

Claim 1(b) instructs to compare the skin aging gene expression signature identifier as set out in Tables A-D of the Specification to each the identifiers listed for each instance. The result of the comparison in step (b) leads to the assignment of a connectivity score set out in step (c). The Specification explains that it is “preferential to find materials that tend to reverse one or both of the gene expression signatures. Such materials will have negative connectivity score, and the more negative the score the stronger the negative connection.” Spec. 65:5–7. Figure 7, reproduced below, shows an example of extreme negative connectivity.



**FIG. 7**[, reproduced above,] schematically illustrates an extreme example of a negative connectivity between signature 94 and the instance 88 comprising the probe IDs 90, wherein the probe IDs of the instance are ordered from most up-regulated to most down-regulated. In this example, the probe IDs of the up list 93 (e.g., X<sub>1</sub>, X<sub>2</sub>, X<sub>3</sub>, X<sub>4</sub>) correspond exactly with the most down-regulated genes of the instance 88, and the probe IDs of the down list 95 (e.g., X<sub>5</sub>, X<sub>6</sub>, X<sub>7</sub>, X<sub>8</sub>) correspond exactly to the most up-regulated probe IDs of the instance 88.

Spec. 35:14–21. When “the up-regulated genes of the signature are predominantly found among the down-regulated genes of the instance, and

vice versa, this is scored as negative connectivity.” Spec. 35:6–8. Based on these disclosures in the Specification, we agree with Appellant that the term negative connectivity score as claimed is sufficiently described.

The preponderance of the evidence of record does not support Examiner’s conclusion that step (d) of claim 1 is indefinite. Accordingly, we reverse the rejection of claim 1 and any of its dependents.

## *II. Written Description*

Examiner found that the Specification does not provide adequate written descriptive support for the “claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus.” Ans. 4. Examiner acknowledges that the Specification “describes tests of carob seed extract and artichoke leaf extract.<sup>3</sup> [But maintains that n]o description is provided of a genus of cosmetic agents having a connectivity score with a negative correlation.” *Id.* Examiner’s position is “[i]f the cosmetic agents of the claims are not already known in the literature, then it is Appellant’s responsibility to disclose them in the specification.” *Id.* at 10. “Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required.” Ans. 6 (citing *Fiers v. Revel*, 25 USPQ2d

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<sup>3</sup> The Specification disclosed that both artichoke leaf extract and carob seed extract linked negatively to photo-aging gene expression. See Spec. 64–74 (Examples 6 and 7). Although the description of two agents is not a great number, it is also not zero. Additionally, we note that the two cosmetic agents were obtained using the imbedded screening method set out in steps (a)–(c) of claim 1.

1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, . . . [927 F.2d 1200 (Fed. Cir. 1991)].”

Appellant takes the position that there is a strong presumption that adequate written description is found in an application as filed. Appeal Br. 3–4. Specifically, Appellant contends that “claim 1 does not attempt to claim a particular genus of cosmetic agents *per se*.” *Id.* at 4. The Specification additionally “indicates that a negative connectivity score occurs when the up-regulated genes of the signature are predominantly found among the down-regulated genes of the instance.” Reply Br. 3. Appellant contends that the “techniques for creating instances and identifying/screening cosmetic agents associated with those instances are clearly described in the specification.” *Id.* Appellant contends that “[i]n contrast with *Fiers*, pending claim 1 recites a **specific** method of identifying a **cosmetic agent**, and the present application provides numerous specific examples of cosmetic agents. Thus, *Fiers* is not applicable to the facts of the present case.” *Id.* Additionally, Appellant notes that *Amgen* is not relevant to the facts in this case. *Id.* at 4.

On this record, we find that Appellant has the better position. Claim 1 is directed to a method of making a cosmetic skin care composition by incorporating cosmetic agents. *See* claim 1 (preamble and step (e)). The written description requirement “serves a teaching function, as a ‘*quid pro quo*’ in which the public is given ‘meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.’” *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 922 (Fed. Cir. 2004).

We find that the Specification describes at least two compositions, artichoke leaf extract and carob seed extract, that possess the requisite negative connectivity score for incorporation into the cosmetic composition. *See* Spec. 64–74 (Examples 6 and 7). Additionally, the activity of these two compounds was determined using the screening method set out in steps (a)–(c) of the claim 1. *See* Spec. 65 (“Of the 20 candidates screened, 2 showed consistent connections to the photo-aging gene expression signatures when tested in BJ fibroblasts” (Human skin fibroblasts (BJ cell line from ATCC, Manassas, VA))). Thus, the disclosure in the Specification establishes that the screening method is not just hypothetical but is actually proven to work and thereby satisfies the basic *quid pro quo* underlying the patent system. *See Rochester*, 358 F.3d at 929.

Examiner’s rejection, however, focuses on the list of cosmetic agents having a negative connectivity score as recited in step (d) of claim 1. *See* Final Act. 10 (“A computational method of screening for agents may not suffer the same deficiencies, but the claims make clear that the method is a method of making a skin care product. Thus written description of the agents to be incorporated in the skin care product is required”). By focusing on the list, Examiner ignores the additional claim elements found in steps (a)–(c) of the claim that incorporates the screening method. As discussed above, the Specification establishes that the disclosed screening method successfully identified known cosmetic compounds that have a requisite negative connectivity score. In other words, the Specification provides sufficient guidance that would steer the skilled practitioner toward compounds useful for successfully carrying out the claimed method of producing a skin care composition.

On this record, the preponderance of the evidence of record does not support Examiner's conclusion that Specification lacks sufficient written descriptive support for the method recited in claim 1. Accordingly, we reverse the rejection of claim 1 and any of its dependents.

*III. Abstract Idea*

Examiner's position is that "[t]he idea of using gene expression patterns to identify agents is an abstract idea and thus the claims must be analyzed for subject matter eligibility under USC 101." Ans. 6. In particular, "Examiner's position is that the specific steps implemented on the computer and the algorithm/workflow used to identify cosmetic agents are abstract ideas that have been implemented on a computer." Ans. 11.<sup>4</sup>

Appellant contends that Examiner's 35 U.S.C. § 101 analysis is oversimplified. Appeal Br. 7. Appellant contends that Examiner (1) did not identify a judicial exception, (2) did not identify the additional elements, and (3) did not consider the combination as a whole. *See id.* at 6. Specifically, Appellant contends that "the limitation of accessing the database in step (a) and the **physical step** of incorporating the cosmetic agent into a skin care composition in step (e) [of claim 1]. Both of these steps require some form of action that cannot be performed in the human mind." *Id.* at 8.

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<sup>4</sup> Examiner's rejection under 35 U.S.C. § 101, is based on the claims being directed to an abstract idea. *See* Ans. 6–7, 12. Examiner acknowledges that the use of skin care agents that prevent aging touches a "law of nature" (*see id.* at 7) but ultimately concludes that "[t]he claims, in their current form, lack any data, correlations or facts that could be construed as laws of nature . . . because the 'judicial exception' in the claims is an abstract idea, not a law of nature" (*id.* at 12).

We analyze this appeal under the framework set forth by the Supreme Court in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), and applied by our reviewing court in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015). As the *Ariosa* court explained:

In *Mayo* . . . , the Supreme Court set forth 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. First, we determine whether the claims at issue are directed to a patent-ineligible concept. If the answer is yes, then we next consider the elements of each claim both individually and “as an ordered combination” to determine whether additional elements “transform the nature of the claim” into a patent-eligible application. The Supreme Court has described the second step of this analysis as a search for an “inventive concept”—i.e., an element or combination of elements that is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.”

*Id.* at 1375 (alteration in original) (internal citations omitted).

We begin with the first step of the *Mayo* test, namely, whether a claim is “directed to” a patent-ineligible concept. On January 7, 2019, the Director of the USPTO issued the “2019 Revised Patent Subject Matter Eligibility Guidance” (“Revised Guidance”), which provides further details regarding how the Patent Office analyzes patent-eligibility questions under 35 U.S.C. § 101. 84 Fed. Reg. 50–57 (Jan. 7, 2019). Under the Revised Guidance, the first step of the *Mayo* test (i.e., Step 2A of the Revised Guidance) is “a two-prong inquiry.” *Id.* at 54. In prong one, we evaluate whether the claim recites a judicial exception, such as a law of nature, natural phenomenon, or an abstract idea. *Id.* If the claim recites a judicial exception, the claim is further analyzed under prong two, which requires “evaluat[ion of] whether

the claim recites additional elements that integrate the exception into a practical application of that exception.” *Id.* The Revised Guidance explains that, “[i]f the recited exception is integrated into a practical application of the exception, then the claim is eligible at Prong Two of . . . Step 2A [of the Revised Guidance].” *Id.*

*Step 2A – Prong One*

In our analysis, we must determine whether Appellant’s claims are directed to a judicial exception. We select claim 1 as representative. Concepts determined to be abstract ideas, and thus patent ineligible judicial exceptions, 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); *Diamond v. Diehr*, 450 U.S. 175, 191 (1981)); and mental processes (*Gottschalk v. Benson*, 409 U.S. 63, 69 (1972)). With respect to the first prong of Step 2A of the Revised Guidance, we do not agree with Examiner that independent claim 1 recites a patent-ineligible abstract idea.

Appellant’s claim 1 is not directed to a method of organizing human activity, nor has Examiner established that the accessing, comparing, and assigning steps of Appellant’s claimed method could practicably be performed in the human mind, and, therefore, amount to a mental process. *See* Appeal Br. 8 (“the limitation of accessing the database in step (a) and the **physical step** of incorporating the cosmetic agent into a skin care composition in step (e). Both of these steps require some form of action that cannot be performed in the human mind”). The final category of abstract ideas identified by the courts is mathematical concepts. *See* 84 Fed. Reg. at 52. Appellant’s claim 1 does not recite a mathematical concept, such as a

specific mathematical algorithm or formula. *See Parker*, 437 U.S. at 586; *Diehr*, 450 U.S. at 187. Although Appellant’s claim 1 may recite steps that tangentially involve mathematics (e.g. comparing two lists by use of a computer), claim 1 does not recite a specific mathematical concept such as an algorithm or formula. Appellant’s claim 1, therefore, does not recite an abstract idea that would make it patent-ineligible under 35 U.S.C. § 101 (*see* App. Br. 7 (“[C]laim 1 and 7–18 are not directed to a judicial exception.”); *see also* Reply Br. 5). Because we find that claim 1 does not recite a judicial exception, our analysis of the 35 U.S.C. § 101 rejection could end here. For the reasons discussed below, we additionally determine that prong two of step 2A of the Revised Guidance is also not met.

*Step 2A – Prong Two*

Even if we were to interpret Appellant’s claim 1 to recite a patent-ineligible mathematical concept, under the Revised Guidance, we would then also determine “whether the claim recites additional elements that integrate the exception into a practical application of that exception.” 84 Fed. Reg. at 54. Limitations that are indicative of integration into a practical application include applying the natural law to effect a particular treatment or prophylaxis for a disease or medical condition. *See, e.g., Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1066–68 (Fed. Cir. 2011); *see Vanda Pharms. Inc. v. West-Ward Pharms. Int’l Ltd.*, 887 F.3d 1117, 1134–35 (Fed. Cir. 2018).

Here, claim 1 is directed to making a skin care composition by incorporating cosmetic agents that have a negative connectivity score and thereby incorporates beneficial substances that counter act the effects of photo-aging or intrinsic aging into a practical formulation for application to

the skin. *See* Spec. 51:1–3, *see also id.* at 65:3–7 (“Since both intrinsic aging and photo-aging are considered adverse conditions, it is preferential to find materials that tend to reverse one or both of the gene expression signatures.”). We agree with Appellant’s and conclude that the physical step of incorporating the cosmetic agent identified in steps (a)–(d) of claim 1 into a skin care composition as set out in step (e) is a practical application of the knowledge gathered in these prior steps and thereby transforms the gathering information into a practical use. *See Classen*, 659 F.3d at 1067–1068.

For the reasons discussed above, we are not persuaded that Examiner has established by a preponderance of the evidence of record that claim 1 is patent ineligible. Accordingly, we reverse the rejection of claim 1 and any of its dependents.

#### SUMMARY

We reverse the rejection of all claims.

REVERSED