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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MICHAEL KOGANOV

Appeal 2019-003552
Application 13/821,775
Technology Center 1600

Before JEFFREY N. FREDMAN, DEBORAH KATZ, and JOHN G. NEW, *Administrative Patent Judges*.

KATZ, *Administrative Patent Judge*.

DECISION ON APPEAL

Introduction

Appellant[1] seeks our review, under 35 U.S.C. § 134(a), from the Examiner's decision to reject claims 1, 4–9, 11–14, 16–21, and 35 (Appeal Brief filed May 7, 2018 ("Br.") 3.)[2]

We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

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[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 ISP Investments LLC (*see* Br. 3.)

[2] Claims 22–34 are withdrawn.

Appellant's Specification provides a *Ficus* serum fraction derived from the cell juice of fresh *Ficus* leaves that "consists essentially of the *Ficus* leaf cell cytoplasm." (Spec. ¶ 43.) The Specification discloses that *Ficus* serum fraction produces superior skin lightening effects in comparison to traditional *Ficus* extract when applied to the skin. (*Id.* ¶ 45.) The Specification discloses the *Ficus* Serum Fraction of the current invention is prepared by separating the fresh cell juice found in the plant leaves from the rest of the plant matter, in contrast by solvent extraction. (*Id.* ¶ 47.) The Specification discloses that cell juice contains "the full spectrum of compounds" found in fresh *Ficus* leaves, because there is no solvent extraction. *Id.* The Specification discloses fractionating cell juice to remove organelles, unwanted pigments, and proteins, thereby producing a personal care ingredient having a desirable combination of functional properties. *Id.* ¶¶ 66–67.

Appellant's claim 35 recites:

> A Ficus serum fraction isolated from cell juice derived from fresh Ficus leaves,
>
> wherein said Ficus serum fraction is substantially free of pheophorbides and is substantially free of proteins as measured by the Kjeldahl method, and
>
> wherein said Ficus serum fraction has biological activity capable of reducing skin hyperpigmentation.

(Br. 26.) Appellant's claim 1 is a product-by-process claim reciting a *Ficus* serum fraction having substantially identical properties, produced by a process comprising the steps of separating, filtering and fractionating. (Br.

22.) Appellant does not present separate arguments against the rejection of the dependent claims.

We focus on claims 1 and 35 in our analysis below. *See* 37 C.F.R. § 41.37(c)(1)(iv).

The Examiner rejects the claims as follows (Final Office Action mailed May 5, 2017 ("Final Act.")):[3]

Claims	Grounds	Reference	Final Act.
1, 4–9, 11–14, 16–21, and 35	§ 101		2–3
1, 4–9, 11–14, 16–21, and 35	Non-statutory double patenting	Claims 1–7 of App. No. 13/821,868	5–6

Analysis

35 U.S.C. § 101, Non-Statutory Subject Matter

The Examiner rejects claims 1, 4–9, 11–14, 16–21, and 35 under 35 U.S.C. § 101 as being directed to non-statutory subject matter. (Ans. 3.) The Examiner finds the claims are drawn to a natural product isolated from *Ficus* leaves comprising *Ficus* serum fraction. (*Id.* at 4.) The Examiner finds "compounds of *Ficus* Serum Fraction are structurally the same as naturally occurring ingredients found in leaves of *Ficus*." (*Id.* at 5.) The Examiner finds isolates from the different process of extractions are not markedly different from their closest naturally occurring counterpart because there is no indication that extraction and partial purification causes isolates

[3] The Examiner withdrew a rejection of claims 1, 4–9, 11–14, 16–21, and 35 as being indefinite under 35 U.S.C. § 112, second paragraph (Examiner's Answer mailed January 25, 2019 ("Ans.") 7).

comprising the claimed compositions to have any characteristic different from naturally occurring chemicals found in *Ficus* extract. (*See id.*)

Although 35 U.S.C. § 101 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 . . . ," the Supreme Court has determined that there are exceptions to what is patentable. Specifically, "laws of nature, natural phenomena, and abstract ideas" are not eligible subject matter. *See Diamond v. Diehr*, 450 U.S. 175, 185 (1981). To determine if claimed subject matter is statutorily eligible in light of these judicial exceptions the Supreme Court has articulated a two-step framework in *Mayo Collaborative Services v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012), and later cases. Specifically,

> [f]irst, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. . . . If so, we then ask, "[w]hat else is there in the claims before us?" . . . To answer that question, 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.

Alice Corp. v. CLS Bank Int'l, 573 U.S. 216, 217 (2014) (quoting *Mayo*, 566 U.S. at 78). Thus, we must determine whether the claim is directed to a judicially determined patent-ineligible concept and, if so, then ask if there is anything in the claim that transforms it into patent-eligible subject matter.

The USPTO recently published revised guidance on the application of § 101. (*See* USPTO, *2019 Revised Patent Subject Matter Eligibility Guidance*, 84 Fed. Reg. 50–57 (2019) ("2019 Guidelines").) After determining that claimed subject matter falls within the four categories of

patentable subject matter identified in 35 U.S.C. § 101, the 2019 Guidelines provides a "revised step 2A," which corresponds to the first step of the *Alice/Mayo* test articulated above, to determine whether a claim is directed to a judicial exception. (*See* 2019 Guidelines, 84 Fed. Reg. at 53–54.) In a first prong of revised step 2A, the Examiner must determine whether the claim recites a judicial exception. (*See id.* at 54.) If a judicial exception is identified, the second prong requires a determination of whether the judicial exception is integrated into a practical application. (*See id.*) If so, the inquiry ends and the claim is determined to be directed to eligible subject matter under the 2019 Guidelines. (*See id.* at 54 ("When the exception is so integrated [into a practical application], then the claim is not directed to a judicial exception (Step 2A: NO) and is eligible. This concludes the eligibility analysis.").) If not, the analysis continues to determine if the claim provides an inventive concept. (*See id.* at 56.)

We first examine whether the claims recite a judicial exception, specifically a product of nature as found by the Examiner. Appellant argues that the *Ficus* serum fraction is produced by a man-made process that does not occur in nature, and thus, "is a man-made fraction that would not and could not be a naturally occurring product." (Br. 8 (emphasis omitted).) Appellant argues that each process step of separating, filtering, and fractionating, does not naturally occur in nature. (*Id.* at 9.) Appellant contends "[i]nstead, the process now recited in claim 1 and its resulting *Ficus* Serum Fraction are not naturally occurring processes or products, and are patent eligible subject matter." (*Id.*)

We agree with Appellant that the claimed *Ficus* serum fraction is not produced by a naturally occurring process. However, this does not end the

inquiry. Merely isolating a natural product and thereby creating a nonnaturally occurring material does not necessarily result in patent eligible subject matter. *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 593 (2013). In *Myriad*, the Supreme Court held claims directed to isolated DNA were not "saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule." *Id.* Rather, in order to be patent eligible, a "nonnaturally occurring manufacture or composition of matter" must possess "markedly different characteristics from any found in nature." *Id.* at 590–91 (citing *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)). We apply the same analysis to the *Ficus* serum fraction, as claims 1 and 35 recite isolated naturally occurring components of *Ficus* plants that have been separated from other cellular materials. (*See* Spec. ¶¶ 43, 47, 66–67.)

Appellant contends "the claimed *Ficus* Serum Fraction has bioactive properties and characteristics that are not found in the naturally occurring cell juice or sap of the *Ficus* plant that would be found in nature." (Br. 9.) Particularly, Appellant contends the claimed "*Ficus* Serum Fraction is 'substantially free of pheophorbides' and 'substantially free of proteins.'" *Id.* Appellant cites to paragraphs 74–100 of the Specification as evidence that the "*Ficus* Serum Fraction as claimed is markedly different from Ficus extracts found in nature." (Br. 10.)

Appellant must identify evidence that there are markedly different characteristics between the claimed product and the product in nature, i.e., *Ficus* cell juice for their argument to be persuasive. The cited paragraphs of the Specification disclose differences between the *Ficus* serum fraction and "traditional *ficus* extracts" prepared by solvent extraction or from dry leaves

as a source. (Spec. ¶¶ 37, 74–100 (emphasis added).) Appellant does not direct us to any comparison between *Ficus* Serum Fraction, and "naturally occurring cell juice." (*See* Br. 9.) Therefore, we do not find Appellant's arguments regarding paragraphs 74–100 probative of whether the claimed *Ficus* serum fraction is markedly different from the corresponding natural product.

In contrast, we find Appellant's Specification provides evidence that the properties of the claimed composition are shared by the naturally occurring cell juice from which the *Ficus* serum fraction is derived. According to Appellant's Specification, "cell juice . . . contains the full spectrum of compounds found in fresh ficus leaves. In contrast, extracts contain only the narrow range of compounds . . . . Thus, the resulting *Ficus* Serum Fraction contains a much broader range of potentially active compounds than does an extract." (Spec. ¶ 47.) The Specification discloses that "[t]he solids contain the biologically active portion of the [*Ficus* serum fraction] or extracts. Thus, the higher the solids content the higher the botanical activity. The [*Ficus* serum fraction] has a higher solids content as compared to traditional water-soluble ficus extracts." (*Id.* ¶ 88.) Accordingly, the claimed "biological activity capable of reducing skin hyperpigmentation" appears to result from concentrating the active compounds existing naturally in the cell juice rather than obtaining any non-naturally occurring active compounds. (*See id.* ¶ 98.)

We further consider that the claimed fraction is "substantially free of pheophorbides" and "substantially free of proteins." The Specification discloses that pheophorbides are known skin photosensitizers and biological toxins. (Spec. ¶ 82.) The Specification discloses proteins can cause contact

dermatitis in sensitive individuals. (*Id.* ¶ 84). The Specification discloses "[a]t levels normally found in plants, these materials typically do not raise concern. However, when plant materials are concentrated, such as through processing, the relative concentration present dramatically increases and can create safety concerns." (*Id.* ¶ 81.) The Specification does not provide any evidence that naturally occurring cell juice contains an amount of pheophorbides or proteins that would create safety concerns, particularly where these compounds previously existed in traditional extracts. (*See id.* ¶ 83). Appellant's Specification states:

> Although the present investigators have also shown by way of example that traditional ficus extracts can deliver a hyperpigmentation benefit, these traditional extracts are not as efficacious and they have properties making them less suitable and thus less desirable for use in cosmetic compositions.

(Spec. ¶ 99.) The Specification continues by explaining that the *Ficus* serum fraction has higher levels of certain ingredients, such as tannins, that reported to be beneficial to combat aging, Appellant does not direct our attention to a portion of the Specification that indicates there would be safety concerns with naturally occurring juice. Again, the differences observed with *Ficus* serum fraction appear to result from concentrating the active compounds existing naturally in the cell juice rather than because of any non-naturally occurring active compounds.

We find the claimed *Ficus* serum fraction containing naturally occurring active compounds and excluding naturally occurring undesired compounds to be similar to the claimed mixtures in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). The Supreme Court held the

> [d]iscovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable.

Id. at 131. Moreover, the Court found "[t]he combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had." *Id.*

The facts are also similar to those in *Bhagat*, where our reviewing court found that "the Applicant has not shown that the claimed mixtures are a 'transformation' of the natural products, or that the claimed mixtures have properties not possessed by these products in nature." *In re Bhagat*, 726 F. App'x 772, 779 (Fed. Cir. 2018) (non-precedential). Likewise, Appellant has not shown that the *Ficus* serum fraction is a transformation of the natural product, or that the claimed fraction has properties not possessed by the natural product. Accordingly, we are not persuaded that the claimed *Ficus* serum fraction is markedly different from the natural product and we find that the claims recite a judicial exception, i.e., a product of nature.

After identifying the judicial exception, we examine whether the judicial exception is integrated into a practical application. (2019 Guidance, 84 F3d. Reg. at 55.) In particular, we evaluate the claims for additional elements that integrate the natural product into a practical application. *Id.* For example, additional elements may include a particular treatment or prophylaxis for a medical condition or a particular manufacture that is integral to the claims. *Id.* As to the product-by-process of claim 1, we evaluate the patentability of the claim based on the product itself and not its method of production. *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985).

Claims 1 and 35 recite the isolated natural products and the properties thereof, e.g., biological activity. The claims do not include "specific methods of treatment that employ a natural law" or "specific treatment formulations that incorporate natural products." *Cf. Nat. Alternatives Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338, 1348 (Fed. Cir. 2019) ("Although beta-alanine is a natural product, the Product Claims are not directed to beta-alanine. A claim to a manufacture or composition of matter made from a natural product is not directed to the natural product where it has different characteristics and the potential for significant utility.") (internal citations omitted). Unlike claims 1 and 35, the claims in *Natural Alternatives* recited "a human dietary supplement" containing a natural product, e.g., beta-alanine, and methods for using the supplement to increase athletic performance. *See id.* at 1348. Claims 1 and 35 do not include similar additional elements integrating the natural product into a practical application. Accordingly, we find that the claims are directed to the judicial exception.

Finally, we evaluate whether additional elements in the claims recite "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.'" *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1375 (Fed. Cir. 2015). Particularly, we evaluate whether the claims include specific limitations that are not "well-understood, routine, conventional activity previously engaged in by scientists who work in the field." *Mayo*, 566 U.S. at 79. Claim 1 recites a product-by-process, wherein the process includes conventional steps of separating, filtering, and fractionating. *See Ariosa*, 788 F.3d at 1377

("Using methods like PCR to amplify and detect cffDNA was well-understood, routine, and conventional activity in 1997."). Claim 35 recites "substantially free of proteins as measured by the Kjeldahl method," which necessarily incorporates a known and conventional measurement method. There is no evidence that either claim includes unconventional elements relating to the isolation and characterization of the isolated naturally occurring composition. Accordingly, the elements merely append routine and conventional steps to the natural product itself, and thus, do not supply an inventive concept. *Id.* at 1378.

Obviousness-Type Double Patenting

The Examiner provisionally rejected claims 1, 4–9, 11–14, 16–21, and 35 over claims 1–7 of co-pending Application Serial No. 13/821,868. (Final Act. 5.) The claims have since been issued as Patent No. US 9,993,508 B2. (Ans. 16.) Appellant has failed to present arguments against the substantive rejection. (Br. 20.) "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." *Ex parte Frye*, 94 USPQ2d 1072, 1075 (BPAI 2010) (precedential). Accordingly, we summarily affirm the Examiner's rejection.

CONCLUSION

In summary:

Claims Rejected	Basis	Affirmed	Reversed
1, 4–9, 11–14, 16–21, and 35	§ 101	1, 4–9, 11–14, 16–21, and 35	
1, 4–9, 11–14, 16–21, and 35	Non-statutory double patenting	1, 4–9, 11–14, 16–21, and 35	

Claims Rejected	Basis	Affirmed	Reversed
Overall Outcome		1, 4–9, 11–14, 16–21, and 35	

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

AFFIRMED