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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RAFAEL BURGOS, JUAN HANCKE, EVELYN JARA, and MARIA HIDALGO[1]

Appeal 2015-006760
Application 13/076,117
Technology Center 1600

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and RICHARD J. SMITH, *Administrative Patent Judges*.

SMITH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a standardized extract. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

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[1] According to Appellants, the real party in interest is Maqui New Life S.p.a. (Appeal Br. iv.)

STATEMENT OF THE CASE

Claims on Appeal

Claims 61, 63, 65–72, 80–86, 88, and 94 are on appeal.[2] (Claims Appendix, Appeal Br. 17–19.) Claim 61 is illustrative and reads as follows:

61. A standardized extract comprising a plurality of anthocyanins and anthocyanidins, wherein at least about 35% of the composition, by weight, is a plurality of anthocyanins and anthocyanidins and wherein the anthocyanins and anthocyanidins are selected from the group consisting of delphinidin-3-0-sambubioside-5-0-glucoside, delphinidin-3,5-0-diglucoside, cyanidin-3-0-sambubioside-5-0-glucoside, cyanidin-3,5-0-diglucoside, delphinidin-3-0-sambubioside, delphinidin-3-0-glucoside, cyanidin-3-0-sambubioside, and cyanidin-3-0-glucoside; and at least about 15% of the anthocyanins or anthocyanidins or both, by weight, are sugar-free or sugar-containing delphinidins, and wherein the composition is nontoxic.

Examiner's Rejections

1. Claims 61, 63, 65–72, 80–86, 88, and 94 stand rejected under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), second paragraph, as indefinite. (Non-Final 3–4.)

2. Claims 61, 63, 65–72, 80–85, 88, and 94 stand rejected under 35 U.S.C. § 101 as directed to a product of nature. (Ans. 2–9.)[3]

FINDINGS OF FACT

The following findings are included for emphasis and reference convenience.

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[2] Claims 73–79, 89–93, 95, and 96 are withdrawn from consideration. (Non-Final Office Action dated October 10, 2014 ("Non-Final"), at 1–3.)

[3] This is designated as new ground of rejection in the Answer, but the Non-Final Action also presented a § 101 rejection that Appellants address in the Appeal Brief.

FF 1. The Specification states that "[a]nthocyanidins and anthocyanins (anthocyanidins including sugar groups) are a large family of naturally occurring pigments. The color of most fruits, flowers and berries is determined by their content of anthocyanidins and anthocyanins." (Spec. 1, ll. 16–18.)

FF 2. Appellants state "[a]nthocyanidins such as 'delphinidin-3-0-sambubioside-5-0-glucoside' exist in nature," and that "there is no structural difference between delphinidin-3-0-sambubioside-5-0-glucoside in its naturally occurring state and in the claimed (purified) state." (Reply Br. 2.)

FF 3. The Examiner finds that the source of the claimed compounds (*i.e.*, fruit) is non-toxic. (Ans. 12.)

FF 4. The Specification states that "[t]he compositions . . . can also include an andrographolide . . . The andrographolide can be an andrographolide, a deoxyandrographolide, a neoandrographolide, or a mixture thereof, and it may be contained within an extract of a plant of the genus *Andrographis (e.g., Andrographus paniculata)*." (Spec. 3, ll. 9–14.)

FF 5. The Specification states that "the delphinidin-containing *(e.g.,* delphinidin-rich) compositions can include specific compounds such as one or more of: myrtillin, cyanidin, quercetin, a caffeoylquinic derivative, a proanthocyanidin and/or proanthocyanin *(e.g.,* as found in the herba *(e.g.,* leaves) of a plant of the genus *Vaccinium)*." (*Id.* at 2, ll. 11–14.)

DISCUSSION

Issue – 112

Whether a preponderance of evidence of record supports the Examiner's conclusion that claims 61, 63, 65–72, 80–86, 88, and 94 fail to comply with 35 U.S.C. § 112 as indefinite.

Analysis

The Examiner finds that Appellants' use of the word "standardized" in the preamble is indefinite, stating that "[i]n order to be 'standardized' there must be a description of what the extract is standardized against. The specification, as originally filed, does not define what [Appellants] regard[] as 'standardized' and what the extract(s) is/are standardized against or what they are in comparison to." (Non-Final 4.) Appellants argue that the Examiner requested that Appellants replace the originally filed preamble term "composition" with "standardized extract," and that, in any event, "standardized extract" is merely a preamble that is given no weight. (Appeal Br. 1–3.) The Examiner does not respond to Appellants' arguments.

While we take no position on the merits of Appellants' arguments, the absence of a response in the Examiner's Answer calls into question the continued viability of this rejection. Accordingly, we reverse.

Conclusion

A preponderance of evidence of record fails to support the Examiner's conclusion that claims 61, 63, 65–72, 80–86, 88, and 94 fail to comply with 35 U.S.C. § 112 as indefinite.

Issue –101

Whether a preponderance of evidence of record supports the Examiner's conclusion that claims 61, 63, 65–72, 80–85, 88, and 94 are directed to non-statutory subject matter.

Principles of Law

On issues of patent eligibility, we "first determine whether the claims at issue are directed to a patent-ineligible concept," such as laws of nature, natural phenomena, and abstract ideas. *Alice Corp. Pty Ltd. v. CLS Bank*

Int'l, 134 S.Ct. 2347, 2355 (2014) ("*Alice*"). If this threshold is met, we move to the second step of the inquiry and "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.* (quoting *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289, 1297–98 (2012) ("*Mayo*")).

Analysis

We adopt the Examiner's findings and agree with the Examiner's conclusion that claims 61, 63, 65–72, 80–85, 88, and 94 are directed to non-statutory subject matter.[4] (Ans. 2–13.) The rejection is affirmed and Appellants' arguments are addressed below.

We address the claims in three groups, with (1) claim 61 representative of claims 61, 63, 72, 80, 82, 88, and 94, (2) claim 65 representative of claims 65–68 and 83–85, and (3) claim 69 representative of claims 69–71 and 81.

Claim 61

The Examiner finds that the composition of claim 61 is "not markedly different from [its] closest naturally occurring counterpart because there is no indication that extraction and partial purification has caused the anthocyanins and anthocyanidins that comprise the claimed composition[] to

[4] The rejection of claim 86 under 35 U.S.C. § 101 is withdrawn (Ans. 9), and, as set forth above, the rejection of claim 86 under § 112 is reversed.

have any characteristics that are different from the naturally occurring anthocyanins and anthocyanidins in maqui fruit." (Ans. 4.)

Appellants respond by arguing that the Supreme Court decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107 (2013) ("*Myriad*"), supports the patentability of claim 61 because the claimed extract is "purified." (Reply Br. 1–3.) Appellants also argue that, unlike the claims in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948) (*Funk Bros.*), "the instant claims do not preempt the general idea of combining anthocyanins and anthocyanidins" and "the instant invention does not have 'the same effect it always had' in nature." (Appeal Br. 12–14, citing *Funk Bros.*, 333 U.S. at 131.) In particular, Appellants argue that "by providing these compounds in a concentrated form" the claimed compositions "acquire a different use" when compared to the amount of fresh *maqui* fruit one would otherwise have to consume daily in the absence of the concentrated form. (Appeal Br. 13–14.)

We find that the Examiner has the better position. Pursuant to the first step of the *Alice* patent-eligibility framework, we find that claim 61 is directed to a patent-ineligible product of nature. (FF 1–3.) *See Mayo*, 132 S.Ct. at 1293. Claim 61 includes compositions in which naturally-occurring anthocyanidins and anthocyanins have been combined. Consequently, claim 61 is analogous to the claims in *Funk Bros.*, where the Supreme Court "considered a composition patent that claimed a mixture of naturally occurring strains of bacteria" and held that "the composition was not patent eligible because the patent holder did not alter the bacteria in any way." *Myriad*, 133 S.Ct. at 2117 (discussing *Funk Bros.*). Here, Appellants acknowledge the lack of a structural difference between the naturally

occurring and claimed delphinidin-3-0-sambubioside-5-0-glucoside (FF 2), and, as in *Funk Bros*., the claimed invention merely combines naturally occurring biological compounds and does not change them in any way other than purification. Moreover, the fact that claim 61 (and other claims) recite relative amounts (concentrations) of the compounds in the mixture does not save those claims because several of the claims held patent ineligible in *Funk Bros.* also recited relative amounts of the bacterial species in the mixture. *See Funk Bros.*, 333 U.S. at 128, n.1 (*e.g.*, claims 6, 7, and 13.)

In the second step of the *Alice* framework, we review the claims to ascertain whether the product of nature has been sufficiently transformed, or ultimately possess "markedly different characteristics from any found in nature," so as to become patent eligible. *See Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980). Here, notwithstanding Appellants' "different use" argument, there is no evidence of record that the claimed compounds function differently in the extract of claim 61 than they function, either independently or in combination, in nature. Like the facts of *Funk Bros.*, the evidence indicates that the Appellants have done nothing more than bring together natural compounds in a particular composition. Moreover, contrary to Appellants' arguments, *Myriad* teaches that purification "is not an act of invention."[5] *Myriad*, 133 S.Ct. at 2117–18.

[5] Appellants' argument regarding preemption is also unpersuasive because "the absence of complete preemption does not demonstrate patent eligibility." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015).

Appellants' claimed extract comprises natural biological compounds, and the concentration or purification of those compounds does not change any functional characteristic thereof or create a different use from that found in nature. Thus, claim 61 fails under the second *Alice* step.

We affirm the rejection of claim 61 under 35 U.S.C. § 101. Claims 63, 72, 80, 82, 88, and 94 were not argued separately and fall with claim 61.

Claim 65

Claim 65 is dependent on claim 61, and recites "further comprising an andrographolide, wherein the andrographolide constitutes, by weight, at least about 10% of the composition." (Appeal Br. 17.) Moreover, the Examiner notes that, from Examples 18 and 27 in the Specification, "it appears that the addition of andrographolide to a composition comprising anthocyanins and anthocyanidins results in a markedly different characteristic." (Ans. 6.) However, the Examiner also notes that the amounts of anthocyanins/anthocyanidins and andrographolides in the referenced examples "encompasses only a part of the range of amounts claimed" and that "[t]here is no indication that the amounts of andrographolide across the entire range as claimed imparts those or any other markedly different characteristics on a composition comprising anthocyanins and anthocyanidins as claimed." (*Id.*) Appellants respond by acknowledging that "the claimed range is broader than the various ranges used in the inventors' Examples," but that the Examiner has not met the burden of showing that the claimed range is inoperable. (Reply Br. 3–4.)

We find that the Examiner has the better position, and that claim 65 is patent-ineligible for the same reasons as set forth above regarding claim 61. (FF 1–4.) Moreover, the issue is not whether the claimed range is

inoperable. Rather, the issue is that, while claims limited to compositions according to Specification Examples 18 and 27, that show a markedly different characteristic, may be patent eligible, there is no evidence on this record to indicate that those compositions, and corresponding markedly different characteristics, would be applicable across the entire range as claimed. Moreover, because the Examiner established a prima facie case of unpatentability under § 101, the burden of coming forward with evidence or argument shifted to Appellants. *See In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

We affirm the rejection of claim 65 under 35 U.S.C. § 101. Claims 66–68 and 83–85 were not argued separately and fall with claim 65.

Claim 69

Claim 69 is dependent on claim 61, and recites "further comprising a composition that comprises at least one compound selected among myrtillin, quercetin, cyanidin, caffeoylquinic derivatives, and proanthocyanidins." (Appeal Br. 17.) The Examiner states that "there is no indication that the amounts of the additional compound claimed in the compositions results in a markedly different characteristic for the composition as compared to the anthocyanins and anthocyanidins in maqui fruit which lack that additional compound." (Ans. 7.) The Examiner does note that, from Example 27 in the Specification, "it appears that the addition of an extract of Vaccinium (which comprises at least some of myrtillin, quercetin, [cyanidin], caffeoylquinic derivatives and proanthocyanidins) to a composition comprising anthocyanins and anthocyanidins results in a markedly different characteristic" but that "there is no indication that any one of myrtillin, quercetin, [cyanidin], caffeoylquinic derivatives and proanthocyanidins in

the unspecified amounts or particular ratios as claimed resulted in a markedly different characteristic when present in the claimed compositions also comprising anthocyanins and anthocyanidins." (*Id.* at 7–8.) Appellants respond by arguing that the Examiner has not met the burden of showing that the claimed range is inoperable. (Reply Br. 4.)

We find that the Examiner has the better position, and that claim 69 is patent-ineligible for the same reasons as set forth above regarding claim 61. (FF 1–5.) Again, the issue is not whether the claimed range is inoperable. Rather, while the Examiner acknowledges a markedly different characteristic with respect to Example 27, we agree with the Examiner that "there is no indication that any one of [the compounds recited in claim 69] in the unspecified amounts or particular ratios as claimed resulted in a markedly different characteristic when present in the claimed compositions also comprising anthocyanins and anthocyanidins." (Ans. 8.) *See In re Oetiker*, 977 F.2d at 1445.

We affirm the rejection of claim 69 under 35 U.S.C. § 101. Claims 70, 71, and 81 were not argued separately and fall with claim 69.

Conclusion

A preponderance of evidence of record supports the Examiner's conclusion that claims 61, 63, 65–72, 80–85, 88, and 94 are directed to non-statutory subject matter.

SUMMARY

We reverse the rejection of claims 61, 63, 65–72, 80–86, 88, and 94 for failure to comply with 35 U.S.C. § 112 as indefinite.

We affirm the rejection of claims 61, 63, 65–72, 80–85, 88, and 94 under 35 U.S.C. § 101 as being directed to non-statutory 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-IN-PART