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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/405,920	02/27/2012	Regina Celia Bertoldo de Barros	621.002US2	3767
97462	7590	09/24/2018	EXAMINER	
Mark A. Litman & Associates, P.A. 7001 Cahill Road, Ste. 15A Edina, MN 55439			FIEBIG, RUSSELL G	
			ART UNIT	PAPER NUMBER
			1655	
			MAIL DATE	DELIVERY MODE
			09/24/2018	PAPER

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* REGINA CELIA BERTOLDO DE BARROS,  
MICHELE ANN MAJESKI, FREDERIC JOHN RIGELHOF,  
and LEE KENT FRENCH<sup>1</sup>

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Appeal 2017-009906  
Application 13/405,920  
Technology Center 1600

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*Before* DONALD E. ADAMS, JOHN G. NEW, and  
JOHN E. SCHNEIDER, *Administrative Patent Judges.*

NEW, *Administrative Patent Judge.*

DECISION ON APPEAL

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<sup>1</sup> Appellants state that the real party-in-interest is Suntava, LLC. App. Br. 3.

## SUMMARY

Appellants file this appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claims 1–17 and 20–30, which stand rejected as unpatentable under 35 U.S.C. § 101 as being directed to nonstatutory subject matter.

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

We AFFIRM.

## NATURE OF THE CLAIMED INVENTION

Appellants' invention is directed to the extraction of anthocyanin pigments/dyes from natural, hybrid, or inbred com kernels by adding corn kernels with less than 5% by weight of corn kernels comprising broken kernels to an aqueous medium to form an aqueous-com medium. Abstr.

## REPRESENTATIVE CLAIM

Claim 1 is representative of the claims on appeal and recites:

1. An aqueous composition comprising an extraction product from unbroken designed species hybrid corn kernels comprising an aqueous composition separated from the unbroken com kernels having at least 0.5% by weight of anthocyanin content in water of the aqueous composition the anthocyanin content characterized as having less than 65 % by weight of non-acylated anthocyanin and at least 35% by weight of acylated anthocyanin and at least 11 chromatographic peaks representing distinct anthocyanin compounds.

App. Br. 28.

## ISSUES AND ANALYSES

We are persuaded by, and expressly adopt, the Examiner's findings, reasoning and conclusions establishing that Appellants' claims are *prima facie* directed to nonstatutory subject matter. We address the arguments raised by Appellants below.

### *Issue*

Appellants argue that the Examiner erred in finding that Appellants' claims are directed to a phenomenon of nature and are, consequently, unpatentable. App. Br. 10.

### *Analysis*

The Examiner finds that Appellants' claims are directed to a composition of matter and, therefore, to patentable subject matter. Final Act. 2–3. However, the Examiner finds, the claims are directed to one of the judicially-created exceptions to subject matter eligibility, *viz.*, a natural phenomenon. *Id.* at 3. Specifically, the Examiner finds, the claims are directed to an extraction product comprising the recited anthocyanin content which is not markedly different from the closest naturally-occurring counterpart, *i.e.*, an extraction product with anthocyanin content from “natural” corn kernels. *Id.*

The Examiner notes that all of the ingredients recited in the claims are natural products that would naturally exist in the corn; therefore, the Examiner finds, the claims involve a judicial exception. Final Act. 3. The Examiner finds that, when given the broadest reasonable interpretation, Appellants' claims are of broad scope. *Id.* The Examiner observes that the

claim term “designed species hybrid” is meant to distinguish the fact that the corn kernels are genetically modified; however, it is not the genetic material that is being claimed, but, rather, the extraction product. *Id.* The Examiner finds that there is no indication in the record of any markedly different characteristics of the extract product of the “designed species hybrid” corn kernels from the extract product of “natural” corn kernels, or of a structural difference between the claimed extract product with the anthocyanin content and the naturally-occurring extract product with anthocyanin content. *Id.* In other words, the Examiner finds, there is no evidence of record that the genetic modification has resulted in any evident structural changes in the extract product. *Id.* Consequently, the claimed extract product and compositions are structurally the same as naturally-occurring counterparts. *Id.* at 3–4.

The Examiner further finds that a change in the ratio or amount of extract does not transform the claims into an exemption from the judicial exception, because amounts/ratios/percentages do not set forth a “markedly different” structure when compared to the naturally-occurring product. Final Act. 4 (citing, e.g., *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)). The Examiner finds that combining naturally-derived ingredients does not amount to a claim which surmounts the judicial exception. *Id.* (citing *Funk Bros. Seed Co. v. Kato Inoculant Co.*, 333 U.S. 127 (1948)). The Examiner therefore concludes that the claims are directed to the “natural phenomenon” exception to Section 101 and are, consequently, not patentable.

Finally, the Examiner finds, the claims are directed to a water extract composition without any other components that could add significantly more to the exception. Final Act. 5.

Appellants argue that the Examiner's rejection poses a conundrum in that the hybrids are admitted in the rejection that they are not "natural" under *Myriad*, but that, upon extraction, the residue (extraction product) is not patent-eligible solely because it is, in the Examiner's findings indistinguishable from some theoretical extraction product from another "natural" corn kernel source. App. Br. 10–11. According to Appellants, the rejection assumes availability in a natural state of a single natural com kernel that is capable of providing the specific spectrum of anthocyanin dye proportions recited in the claims. *Id.* at 11. Appellants contend that this assumption is not supported by evidence of record. *Id.* Appellants argue that the Examiner assumes that there exists, somewhere in the world, a corn kernel that, if extracted, would produce an extraction composition anticipating the composition recited in the claims, thus providing evidence that the claims are directed to a natural product. *Id.* Rather, Appellants argue, their claimed composition is a "natural product" only in the sense that *each individual component may be naturally occurring, but that the combination is unique in nature*, especially in conjunction with its being carried in a water composition without chemical modification or in admixture with ingredients in addition to the extract. *Id.* (emphasis added).

Appellants argue further that the extraction process itself, by use of water, has created a unique composition of matter. App. Br. 12. According to Appellants, the original anthocyanins as claimed exist within cellular structure of the artificial (i.e., hybrid) corn kernel cells in admixture with additional plant content material. *Id.* Furthermore, Appellants assert, the proportions are also the unique result of the mild, non-chemical extraction of the anthocyanins. *Id.*

Appellants note that, during prosecution, they amended the claims to add a substantive limitation and that all claims are now limited to “hybrids,” “hybrids from crosspollination,” “designed species,” or “designed hybrid.” App. Br. 15 (citing Spec. 2, 20). Appellants also point out that claim 22 recites specific and patented designed hybrids (e.g., FAR045 or FAR601<sup>2</sup>). *Id.* Appellants argue that none of these are natural phenomena. *Id.*

Appellants argue further that, in addition to the “inherent ambiguity” of the term “phenomenon of nature,” claim 1 recites an “unnatural combination of proportions of materials within chemical classes.” App. Br. 16. As proof of this argument, Appellants assert that a) these materials do not exist in those proportions within any known species of natural corn kernels; b) the unique combination and proportions of anthocyanin compounds provides a stability of the ingredients and the product; c) the process leaves an essentially whole kernel by-product that is itself stable and of higher commercial value than ground kernel residue from other types of extraction processes; and d) the capability of producing an extract product that is capable of being defined as legally “organic.” *Id.* at 17.

Finally, Appellants argue that, in addition to the claimed composition being not a natural product, and the relative composition of the composition not being found in “natural” strains of corn, the claimed composition has advantageous and unexpected properties not known in the prior art, *viz.*, an improved stability against hydrolysis, the claims do not substantially foreclose others from using the exception. App. Br. 17–19.

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<sup>2</sup> FAR045 and FAR061 are inbred lines of maize. *See* Spec. 18 (citing US Ser. Nos. U.S. Ser. Nos. 12/143,159; 12/143,079).

Appellants also argue that the claims: (1) recite elements/steps in addition to the judicial exception(s) that relate to the judicial exception in a significant way; (2) that the rejection fails to differentiate among the different limitations in the various claims with respect to the single issue of patent-eligibility upon which all claims have been rejected. App. Br. 22–25.

We are not persuaded by Appellants’ arguments.

Under the analytical framework handed down to us by the Supreme Court in *Mayo Collaborative Servcs. v. Prometheus Labs, Inc.*, 566 U.S. 66 (2012), we initially determine whether the claims at issue are directed to a patent-ineligible concept. *Mayo*, 566 U.S. at 78–79. If so, we then 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. *Id.*

Appellants’ claims are directed to a composition of matter, specifically, an aqueous extract of “unbroken designed species hybrid corn kernels” having at least 0.5% by weight of anthocyanin content comprising less than 65% by weight of non-acylated anthocyanin and at least 35% by weight of acylated anthocyanin, and exhibiting at least 11 chromatographic peaks representing distinct anthocyanin compounds. *See* claim 1. We note that, by the language of the claims, Appellants are not claiming a newly-generated strain or breed of corn kernel, but, rather are claiming a composition extracted from *any* strain or breed of corn that meets the compositional limitation recited in the claims, regardless of whether the designed species hybrid was produced by direct genetic manipulation, cross-pollination, or other traditional methods of cross-breeding. *See* Spec. 19–20 (“Thus, any methods using the inbred maize line FAR601 or FAR045 are



contemplated to be within the scope of this invention, e.g., selfing, backcrossing, hybrid production, crosses to other hybrids, inbreds, populations, and the like”).

Anthocyanins are a class of polyphenol that are produced naturally in plants, including corn. *See* Spec. 1:

The present invention relates to the field of *naturally occurring colorants and chemicals from plants*, including genetically modified and cross-pollinated plants, the provision of colorant and chemicals from plants having high levels of specifically desirable colorants and chemicals, and *particularly to corn species that provide significant levels of anthocyanins in products from the corn*.

(Emphases added); *see also id.* at 14 (“Pigments found in fruits and vegetables such as carotenoids, chlorophylls, anthocyanins and anthoxanthins provide color. These are the *natural color pigments* that stain or color the skin when the pigments are applied on the skin”) (emphasis added); *id.* at 7 (“Anthocyanin pigments/dyes are extracted from natural, hybrid or inbred corn kernels by adding the appropriate corn kernels with less than 10% and preferably less than 5% by weight comprised of broken kernels to an aqueous medium to form an aqueous-corn medium”).

Importantly, Appellants’ Specification acknowledges that certain hybrid varieties of corn, particularly those with darker-colored kernels, naturally produce higher concentrations of acylated anthocyanin:

This process is especially of technical and commercial importance in the use of dark color corn (e.g., the black corns, reds corns, purple corns) with the anthocyanin levels defined in the practice of the present invention.... In the process, the anthocyanin may have greater than 55% by weight of anthocyanin as an acid or acylated form of the anthocyanin and

the extract has less than 1.0% solids therein. Where the extract is a first extract from the kernels, it may contain less than 5% by weight of the total starch originally in the kernels and greater than 25% by weight of all anthocyanin originally in the kernels, as later described in detail.

Spec. 7–8. Appellants’ Specification further discloses that certain hybrids can produce anthocyanins in the proportions prescribed by the claims:

One description of a resulting product from the extraction process is an anthocyanin-containing extract from corn comprising a composition that when present in water as 1% to 90% by weight anthocyanin comprises more than 55% by weight of total anthocyanin as an acid or acylated form of anthocyanin. This extract may comprise more than 70% by weight of total anthocyanin as an acid or acylated form of anthocyanin, and the extract may be free of any acids or bases that are not extracted or formed from corn kernels from which the extract has been made. The extract may have corn used in the process that comprises tissues of FAR601, FAR045, hybrids of FAR601, hybrids of FAR045 or a hybrid of both FAR601 and FAR045.

Spec. 49.

To summarize, Appellants’ Specification discloses that anthocyanins, including acid or acylated forms are polyphenol molecules that are naturally produced by corn. Furthermore, it was known in the art that certain strains of corn produce higher levels of acid or acylated forms of anthocyanins, including “FAR601, FAR045, hybrids of FAR601, hybrids of FAR045 or a hybrid of both FAR601 and FAR045.” Spec. 49. Although these may be higher levels of acid or acylated anthocyanins than are found in other wild-type or hybrid strains (Appellants’ Specification provides no evidence of this contention) it is not disputed by Appellants that the anthocyanins in the

aqueous-extraction from corn kernels recited in the claims is structurally or otherwise significantly distinguishable, in either their structure or properties, than anthocyanins as they occur *in situ* in these hybrid strains or in other hybrid or wild-type strains.

Therefore, because we find there is no difference in structure or properties between the anthocyanins *in situ* in the corn kernel and in the water extract, we agree with the Examiner that the anthocyanins thus extracted from corn kernels constitute a natural product and are therefore an unpatentable exception to Section 101. Indeed, Appellants expressly acknowledge that:

[T]he [claimed] composition ... is a “natural product” only in the sense that each individual component may be naturally occurring ..., but that the combination is unique in nature, especially in conjunction with its being carried in a water composition without chemical modification or in admixture with ingredients in addition to the extract.

App. Br. 11–12. That the relative proportion of acid or acylated anthocyanins to non-acylated anthocyanin is produced only in certain inbred or hybrid strains is of no import, because the anthocyanins remain the same. Again, we emphasize that Appellants are not claiming a specific strain of modified corn capable of producing increased levels of anthocyanins, but are claiming only the extracted anthocyanins from any strain of corn capable of synthesizing such levels. At the very least, in those strains the anthocyanins produced, and their relative proportions, are produced naturally by the organism and, in Appellants’ composition, are indistinguishable from their structure and function *in situ*.

Nor are we persuaded that Appellants' composition contains any additional steps that add "significantly more" to Appellants' claimed composition beyond the natural products themselves. *See Mayo*, 566 U.S. at 72–73 (i.e., an "inventive concept" that "amounts to significantly more than a patent upon the ... [ineligible concept] itself"). Appellants' claimed composition comprises: "an aqueous composition separated from the unbroken com kernels." Claim 1. This composition is achieved by soaking the kernels in water (with or without agitation) at a temperature above 35°C and then removing the kernels. *See Spec.* 49–50. This process adds nothing to the anthocyanins in the corn kernels, it merely removes them from inside the kernel into the aqueous solution.

Nor are we persuaded by Appellants' argument that their composition is patentably distinct because: "[t]he original anthocyanins as claimed ... [exist] within cellular structure of ... [the] corn kernel cells in admixture with additional plant content material." *See App. Br.* 12. Within the cells of the plant, anthocyanins exist in a solution *comprising* water, as recited in Appellants' claims. *See Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1348 (Fed. Cir. 2001) (Holding that use of the transition "comprising" in the language of a claim creates a presumption that the claim does not exclude additional, unrecited elements). Appellants point to no limitation of the claim that excludes these other "additional plant content material," and even if they did, they still fail to point out how the anthocyanins in their composition are distinguishable from those *in situ* within the cells of the plant.

Finally, we find that any additional element of the limitations with respect to the extract are no more than well-understood, routine, and

conventional activities in the art. Our reviewing court has recently reminded us that: “The question of whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact” and that “[a]ny fact, such as this one, that is pertinent to the invalidity conclusion must be proven by clear and convincing evidence.” *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2008). We find that preparing an extract of chemicals from plant material by heating it in water, with or without agitation, is well-known in the art and would have been known as a “well-understood, routine and conventional to a skilled artisan.” *See, e.g., Taylors of Harrogate Yorkshire Tea, How to Make a Proper Brew, available at: <https://www.yorkshiretea.co.uk/our-teas/how-to-make-a-proper-brew>* (last visited September 18, 2018).

Finally, Appellants argue that the dependent claims are also allowable because the limitations require: (1) certain concentrations of anthocyanins (claims 7, 8, 10, 11); (2) that the extract be certifiable as organic (claims 2, 6, and 13–16); that the extracts are produced in a powdery form by drying the extract (claims 10 and 11); or (4) come from certain specific patented inbred strains (i.e., FAR045 and FAR601) (claim 22). We agree with the Examiner, however, that none of the limitations of these claims changes the essential nature of the anthocyanin or renders it patentably distinct from its natural form *in situ*. We consequently affirm the rejection of these claims.

We consequently conclude that Appellants’ claims are directed to a non-statutory category of subject matter, i.e., a product of nature, and that any additional elements of the claims add nothing more than well-understood, routine, and conventional activities that do not add significantly

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more than the exception itself. We consequently affirm the Examiner's rejection of the claims.

#### DECISION

The Examiner's rejection of claims 1–17 and 20–30 under 35 U.S.C. § 101 is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED