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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte LEILA STRICKLAND[1]

Appeal 2024-002927
Application 17/467,358
Technology Center 1600

Before ERIC B. GRIMES, JOHN E. SCHNEIDER, and RACHEL H. TOWNSEND, *Administrative Patent Judges.*

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a human milk product, which have been rejected as obvious and as being directed to patent-ineligible subject matter. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

STATEMENT OF THE CASE

Appellant's Specification states that, although breastfeeding is recommended for the first six months of an infant's life, "lactation is a

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[1] Appellant states that the real party in interest is BIOMILQ, Inc. Appeal Br. 3. "Appellant" refers to "applicant" as defined in 37 C.F.R. § 1.42.

physiologically demanding and metabolically intensive process that can present biological and practical challenges for breastfeeding mothers." Spec. ¶ 4. The Specification discloses "live cell constructs . . . and methods of using the same for *in vitro* and/or *ex vivo* production of cultured milk product from cultured mammary cells." *Id.* ¶ 31. "In some embodiments, the cultured milk product is a standardized, sterile cultured milk product." *Id.* ¶ 133.

The Specification states that "[b]reast milk contains low but measurable concentrations of environmental contaminants, health-harming chemicals from industry and manufacturing products that are widely spread in the environment. . . . In some embodiments, the cultured milk product does not comprise or is substantially free of one or more environmental contaminants." *Id.* ¶¶ 135–136.

The Specification also states that "[f]ood proteins with allergenic potential that have been detected in human milk include hen's egg and peanut proteins. There are eight major food allergens[:] . . . milk, egg, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybean allergens." *Id.* ¶ 139. "In some embodiments, the cultured milk product does not comprise or is substantially free of one or more food allergens." *Id.* ¶¶ 139–140.

Claims 1, 3–7, 9, and 10 are on appeal. Claim 1 illustrates the claimed invention and is reproduced below:

> 1. An isolated nutritional human milk product, comprising: (a) at least one human milk protein, (b) at least one human lipid, and (c) at least one human polysaccharide; wherein the isolated nutritional human milk product is sterile, and substantially free of cell culture medium, environmental contaminants or known food allergens derived from a food

> selected from the group consisting of: egg, fish, shellfish, tree nuts, peanuts, wheat, and soybean.

Appeal Br. 20 (Claims App.).

The claims stand rejected as follows:

Claims 1, 3–7, 9, and 10 under 35 U.S.C. § 103 as obvious based on Evans,[2] Boquien,[3] Moller,[4] Rosenfeld,[5] Elimination Diet,[6] and Iannelli[7] (Final Action[8] 8), and

Claims 1, 3–7, 9, and 10 under 35 U.S.C. § 101 as being directed to a natural product and therefore ineligible for patenting (Final Action 3–4).

DISCUSSION

Claim Interpretation

Claim 1 recites a human milk product that is "substantially free of cell culture medium, environmental contaminants *or* known food allergens derived from a food selected from the group consisting of: egg, fish,

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[2] T.J. Evans et al., *Effect of storage and heat on antimicrobial proteins in human milk*, Archives of Disease in Childhood 53:239–241 (1978).
[3] C.-Y. Boquien, *Human Milk: An Ideal Food for Nutrition of Preterm Newborn*, Frontiers in Pediatrics, vol. 6, Article 295, pp. 1–9 (2018).
[4] US 5,576,040, issued Nov. 19, 1996.
[5] US 2007/0010760 A1, published Jan. 11, 2007.
[6] UW Integrative Health, The Elimination Diet, www.fammed.wisc.edu/files/webfm-uploads/documents/outreach/im/handout_elimination_diet_patient.pdf, pp.1–10 (2018).
[7] V. Iannelli, *Keep Kids Healthy*, keepkidshealthy.com/2017/09/24/the-breastfeeding-elimination-diet-for-fussy-babies-with-allergic-colitis/, pp. 1–5 (2017).
[8] Office Action mailed March 15, 2023.

shellfish, tree nuts, peanuts, wheat, and soybean." Claim 1 (emphasis added).

The Examiner interprets the claim language to mean that "claim 1 does not require 'free of food allergens' as it lists [the] alternative limitation of free of 'cell culture medium', 'environmental contaminants' OR 'food allergens', and the 'food allergens' does not require all of the listed food[s] as it requires one selected from the species as claimed." Ans. 19.

Appellant, on the other hand, characterizes the claim language as meaning "the claimed milk products are sterile and free of known allergens. The claimed milk products also differ from naturally occurring human breast milk in that they are free of environmental contaminants." Reply Br. 5.

Appellant's claim interpretation of "or" is more consistent with the Specification than the Examiner's proposed interpretation. "The correct inquiry in giving a claim term its broadest reasonable interpretation in light of the specification . . . is an interpretation that corresponds with what and how the inventor describes his invention in the specification, *i.e.,* an interpretation that is 'consistent with the specification.'" *In re Smith Intl., Inc.*, 871 F.3d 1375, 1382–83 (Fed. Cir. 2017) (quoting *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997)).

Appellant's Specification states that the "invention relates to live cell constructs and methods using the same for *in vitro* and/or *ex vivo* production of cultured milk product from cultured mammary cells." Spec. ¶ 3. The Specification describes live cell constructs comprising "polarized mammary cells compris[ing] an apical surface and a basal surface, where "the basal surface of the mammary cells is in fluidic contact with the culture media"

and "the cultured milk product is secreted from the apical surface of the mammary cells into [an] apical compartment." *Id.* ¶ 8. Thus, "the culture media substantially does not contact the cultured milk product." *Id.* The Specification therefore describes Appellant's invention as a milk product that is isolated from cell culture, but without the milk product coming in contact with cell culture media.

The Specification differentiates the inventive cultured milk product from breast milk due to its lack of environmental contaminants. In particular, the Specification states that "[b]reast milk contains low but measurable concentrations of environmental contaminants," which are "widely spread in the environment" and "partly secreted in breast milk." *Id.* ¶ 135. The Specification states, however, that "[i]n some embodiments, the cultured milk product does not comprise or is substantially free of one or more environmental contaminants." *Id.* ¶ 136.

Similarly, the Specification differentiates the inventive cultured milk product from breast milk with respect to the absence of food allergens. In particular, the Specification states that "[f]ood proteins with allergenic potential that have been detected in human milk include hen's egg and peanut proteins." *Id.* ¶ 139. The Specification states, though, that "[i]n some embodiments, the cultured milk product does not comprise or is substantially free of one or more food allergens." *Id.* ¶ 140.

Thus, read as a whole, the Specification describes the invention as being a cultured milk product resulting from the disclosed *in vitro* or *ex vivo* process using live cell constructs in which culture media is kept separate from the product, which differs from breast milk from a lactating mother by

the absence of environmental contaminants and allergens that might be present because of the food consumed by the mother, or the environment to which she was exposed.

We conclude that the broadest reasonable interpretation of the claim language, when read in light of the Specification, i.e., the interpretation that "most naturally aligns with the [Specification's] description of the invention" as compared to the prior art, requires the claimed product to be substantially free of cell culture medium *and* environmental contaminants *and* at least one of the specified food allergens. *See AstraZeneca AB v. Mylan Pharms. Inc.*, 19 F.4th 1325, 1329 (Fed. Cir. 2021), *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1988).

However, claim 1 expressly states that the product is free of allergens "derived from *a food selected from the group consisting of*: egg, fish, shellfish, tree nuts, peanuts, wheat, and soybean." Claim 1 (emphasis added). The Markush language of claim 1 requires the absence of only *one* of the recited food allergens. *See* MPEP § 2117(I) ("Claim language defined by a Markush grouping requires selection from a closed group 'consisting of' the alternative members.").

Obviousness

Claims 1, 3–7, 9, and 10 stand rejected as obvious based on Evans, Boquien, Moller, Rosenfeld, Elimination Diet, and Iannelli. The Examiner finds that Evans teaches "human milk collected from mothers that is frozen and/or pasteurized; or lyophilized." Final Action 8. The Examiner finds that "human milk contain[s] protein, lipids and polysaccharides according to Boquien." *Id.*

The Examiner finds that Evans "suggest[s] that human milk should be collected in as sterile a manner as possible, however, Evans et al. do not particularly disclose the term 'sterile' as claimed." *Id.* at 9. The Examiner finds, however, that it is "well known in the art that human milk can be sterilized by any means known in the art. For example, Moller et al. teach a process for the sterile filtration of milk." *Id.* Thus, the Examiner concludes that it would have been obvious "to sterilize the human milk of Evans et al. using a filtration process taught by Moller et al. . . . as Evans et al. suggest that the human milk should be as sterile as possible," and Moller teaches that filtration "is effective to remove contaminated microorganisms of the human milk." *Id.* at 9–10.

"Regarding the claimed product substantially free of culture medium," the Examiner finds that "since the frozen, pasteurized, and/or lyophilized human milk of Evans et al. does not involve any culturing steps, the product of Evans et al. does not comprise a cell culture medium." *Id.* at 9.

The Examiner finds that "Evans et al. do not teach that the human milk is free of the environmental contaminant[s]" but "Rosenfeld teach[es] that the contaminants of breast milk would be removed and the contaminants include polychlorinated biphenyls (PCB), dioxin, heavy metals." *Id.* at 11. The Examiner concludes that it would have been obvious "to remove the contaminants taught by Rosenfeld from the human milk of Evans et al. because one skilled in the art would recognize health risks posed by the contaminants according to Rosenfeld . . . , and it is beneficial to remove these contaminants from the milk product of Evans et al." *Id.*

"Regarding food allergens," the Examiner finds that Evans does not teach human milk free of food allergens, but "it is known in the art that food allergen contaminants can be reduced or removed to the level of substantially free by modifying maternal diet omitting any potential food allergens in the diet. This is known as the elimination diet." *Id.* (citing Elimination Diet). The Examiner also finds that "Iannelli teaches that the elimination diet omitting potential food allergens in the diet would reduce or eliminate food allergens contaminating breast milk." *Id.* at 11–12.

The Examiner concludes that it would have been obvious "to obtain human breast milk that is derived from mothers who are in the Elimination diet [to] remove any food allergens harmful for the babies based on the teaching of Iannelli." *Id.* at 12. "[T]hus, one skilled in the art would consider the elimination diet taught by Iannelli in order to remove any potential harmful effect caused by food allergens by removing the sources using the elimination diet with a reasonable expectation of success." *Id.*

We agree with the Examiner that the cited references support a prima facie case of obviousness with respect to Appellant's claim 1. Evans discloses that "[h]uman milk was collected by mothers in their own homes." Evans 239, left col. "Aliquots of milk as it arrived at the milk bank were analysed either raw, after deep freezing for 3 months at –20°C, after lyophilisation and reconstitution, or *after pasteurisation*." *Id.* (emphasis added). Boquien teaches that "[h]uman milk consists of 87% water, 1% protein, 4% lipid, and 7% carbohydrate (including 1 to 2.4% oligo-saccharides)." Boquien 2, left col.

Moller discloses "a process for obtaining sterile milk, wherein the calcium ion content is reduced preferably to half of the amount naturally present . . . and the milk is then filtered to sterility, re-adding calcium ions to restore the natural content, if desired." Moller 1:4–9. *See also id.* at 3:22–24 ("[T]he calcium ions can be re-added under sterile conditions after the sterile filtration, until the original, natural level is reached."). Moller teaches that "[t]he milk obtained by the process of the invention is but little changed in its natural composition; it has all its biological activities . . . , while it is free of bacteria, fungi and spores and stable in the liquid state for months." *Id.* at 3:31–35.

More specifically, Moller teaches that "[t]he reduction of the Ca^{++} ion concentration results in an alteration of the consistency of the milk, so that it now filters better and sterilize filtration through 0.2 µm filters becomes possible." *Id.* at 2:31–34. "The removal of the calcium ions can be performed by using ion exchanger materials, preferably cation exchangers such as . . . ACRISIT A 69." *Id.* at 3:5–9. Moller also teaches that, "[p]referably, the milk is defatted to skimmed milk by conventional methods, such as centrifugation, . . . thereby permitting faster filtration." *Id.* at 3:1–4.

Moller provides a working example in which "1 liter of human mother's milk defatted by centrifugation at 4° C. was passed through a column containing 100 ml of ACRISIT A 69." *Id.* at 5:15–17. "The filtrate was then sterile-filtered directly through EKS depth filter (Seitz)." *Id.* at 5:17–18. Moller states that "[t]he mother's milk obtained was free of

bacteria, fungi and spores and stable in the liquid state for more than 5 months." *Id.* at 5:21–23.

We agree with the Examiner that a person of ordinary skill in the art would have considered it obvious to filter sterilize the human milk described by Evans using the process described by Moller, which provides a reason to combine the references because it teaches that filter-sterilized human milk is free of bacteria, fungi, and spores and is stable in the liquid state (i.e., does not spoil) for over five months. And, although Moller describes removing Ca^{++} ions from the milk before sterilizing, it also suggests adding back Ca^{++} ions after sterilization to restore the naturally occurring level of Ca^{++}.

With regard to the limitation of claim 1 requiring the claimed product to be "substantially free of cell culture medium," we agree with the Examiner that, since Evans' collection process does not involve cell culturing, its product would inherently be free of cell culture medium. Appellant does not dispute this point. *See* Appeal Br. 13–18.

With regard to the claim limitation requiring the claimed product to be "substantially free of . . . environmental contaminants," Rosenfeld discloses that "babies . . . depend on essential nutrients from breast-feeding, but these nutrients and fluids have built up with dangerous chemicals over generations of environmental pollution." Rosenfeld ¶ 24. Rosenfeld states that "the advantages of breastfeeding still outweigh the health risks posed by these contaminants," but "pollutants in breast milk negatively affect the milk's nutritional and protective value." *Id.* ¶ 27.

Rosenfeld discloses that, "with a carbon-based filtration system, binding and removal of contaminants and other chemicals is accomplished

whereby breast milk may be substantially improved in terms of noxious chemicals and toxic elements." *Id.* ¶ 42. "Moreover, [Rosenfeld] discloses a filtration system, comprising, in combination: a filtration medium housed in a cartridge; whereby the filtration medium is in fluid communication with a source of milk and a receptacle for housing filtered milk, and whereby toxins are removed from milk." *Id.* ¶ 44. "Suitable filtration media for the removal of organic compounds include, for example, activated carbon." *Id.* ¶ 70.

Based on the teachings of Rosenfeld, it would have been obvious to a person of ordinary skill in the art to filter Evans' human milk product (either before or after filter-sterilization) through, for example, activated carbon in order to remove environmental contaminants from the milk before it was consumed by a baby. Rosenfeld provides ample reason to do so, because it describes the deleterious effects of various contaminants on humans. *See* Rosenfeld ¶¶ 29–41. The cited references thus would have made obvious a human milk product "substantially free of . . . environmental contaminants," as recited in Appellant's claim 1.

Finally, claim 1 requires the claimed product to be "substantially free of . . . known food allergens derived from *a food selected from* the group consisting of: egg, fish, shellfish, tree nuts, peanuts, wheat, and soybean." Claim 1 (emphasis added). As discussed above, the claim language permits the claimed product to be free of allergens derived from only one of the listed foods, it does not require that all of the listed foods be excluded in order to meet the limitation.

Iannelli states that "[a] breastfeeding elimination diet can be helpful if your baby is overly fussy and might have a milk protein allergy or

intolerance to other foods that you are eating." Iannelli 1. Iannelli states that "you should probably start with milk and dairy foods. Those are the most likely to cause issues with your baby." *Id.* at 2. "If that doesn't work, you can continue to eliminate other foods or food groups from your diet, one at a time until you find what is triggering your baby's symptoms." *Id.* The foods that Iannelli suggests eliminating from a breastfeeding mother's diet include soy, eggs, nuts, peanuts, wheat, fish and shellfish. *Id.*[9]

Thus, it would have been obvious to a skilled artisan to collect Evans' milk product from a lactating mother who did not consume one or more of soy, eggs, nuts, peanuts, wheat, fish and shellfish, in order to avoid a potential allergic reaction or intolerance in the baby to whom the milk was fed. Iannelli provides a reason to select these potential allergen-containing foods, because it teaches that these are foods that often trigger an allergic reaction or intolerance, and thus should be among the first to be eliminated from a nursing mother's diet.

In summary, the cited references would have made obvious all of the limitations of claim 1 to a person of ordinary skill in the art at the time Appellant's invention was made.

Appellant argues that "[t]he milk filtration process disclosed by Evans in view of Moller would not produce a sterile milk product as required by the claims, at least because sub-micron bacteria would remain." Appeal Br.

[9] The Examiner also cites Elimination Diet as evidence that "food allergen contaminants can be reduced or removed to the level of substantially free by modifying maternal diet omitting any potential food allergens in the diet." Final Action 11. Iannelli adequately discloses the claim limitation at issue, so we will not further discuss Elimination Diet.

15. Appellant notes that Moller teaches filtration using a "filter [with a] pore diameter of 0.2 μm," and cites the Koivusaari Declaration[10] as evidence that "bacteria exist that are 'small enough to pass through a 0.1 μm pore size.[']" *Id.* Appellant reasons that "[b]acteria small enough to pass through a 0.1 μm pore size filter would necessarily pass through the 0.2 μm pore size filter disclosed by Moller." *Id.*

This argument is unpersuasive. Dr. Koivusaari states that

> [s]terility as it is known in the field refers to being free of microorganisms. Some bacteria are small enough to pass through a 0.1 μm pore size. *See* Wang et al, "Quantification of the Filterability of *Freshwater Bacteria* through 0.45, 0.22, and 0.1 μm Pore Size Filters and Shape-Dependent Enrichment of Filterable Bacterial Communities," Environ. Sci. Technol. 2007, 41, 20, 7080–7086 (Exhibit A).

Koivusaari Decl. ¶ 5 (emphasis added).[11]

As the Examiner noted, however, "[i]n order to render the appellant's argument effective, there should be an assumption that human breastmilk's microbiome contains bacteria smaller than 0.2 μm." Ans. 17. That is, Appellant's evidence relates to bacteria that are present in a freshwater environment. *See* Wang 7080, right col. ("In the present study, we have used

[10] Declaration under 37 C.F.R. § 1.132 of Katariina Koivusaari, dated Dec. 17, 2022.

[11] At the oral hearing, Appellant presented an argument based on the presence of beneficial bacteria in human milk. *See* Transcript 8–9, 14. However, that argument was not made in the Appeal Brief, and new arguments are not allowed at oral argument. *See* 37 CFR § 41.47(e)(1) ("appellant may only rely on Evidence that has been previously entered and considered by the primary examiner and present argument that has been relied upon in the brief or reply brief," with an exception that is not relevant here).

[flow cytometry] in combination with fluorescence-staining and a regrowth assay . . . to quantify, cultivate, and enrich filterable bacteria from different freshwater samples."); *id.* at 7081, left col. ("Freshwater samples were collected . . . from eight different freshwater environments in Switzerland.").

Appellant has not pointed to evidence showing that *human milk* contains bacteria that would not be effectively removed by filtration through a 0.2 μm filter, as described by Moller. And Moller expressly states that its filtered human milk product was "*free of bacteria*, fungi and spores." Moller 5:21–22 (emphasis added). That disclosure is entitled to a presumption of enablement. *See In re Antor Media Corp.*, 689 F.3d 1282, 1288 (Fed. Cir. 2012) ("[A] prior art publication cited by an Examiner is presumptively enabling barring any showing to the contrary by a patent applicant.").

Appellant also argues that "Rosenfeld does not indicate what level of contaminants are removed from the human milk product, only disclosing that 'breast milk may be substantially ***improved*** in terms of noxious chemicals and toxic elements.' Rosenfeld, Abstract." Appeal Br. 17. Appellant argues that "'Substantially improved' does not mean 'substantially free of.'" *Id.*

This argument is also unpersuasive. Appellant's Specification does not provide a definition of "substantially free of" that would put a specific limit on the amount of environmental contaminants in the claimed milk product. Rosenfeld discloses that, "with a carbon-based filtration system, binding and *removal of contaminants and other chemicals is accomplished* whereby breast milk may be substantially improved in terms of noxious chemicals and toxic elements." Rosenfeld ¶ 42 (emphasis added).

Rosenfeld describes an embodiment in which "[t]he filter media within the nipple shield can comprise a material that is capable of filtering-out endocrine disruptors such as polybrominated diphenyl ethers, polychlorinated biphenyls, dioxins, dibenzofurans, perchlorates, phthalates, and/or heavy metals and radionuclides. Suitable filtration media for the removal of organic compounds include, for example, activated carbon." *Id.* ¶ 70. Rosenfeld also states that "[t]he addition of cationic and anionic resins that absorb cations and anions assists in filtering radionuclides and heavy metals from the breast milk." *Id.* ¶ 73.

Rosenfeld states that "the devices described herein . . . can be used to practice a method of removing organic toxins and/or inorganic toxins, such as halogenated endocrine disruptors, phthalates, radionuclides, heavy metals, and other toxins from breast milk." *Id.* ¶ 94. *See also id.* ¶ 97 ("[A] pump . . . removes contaminated milk from a breast (not shown) into filter cartridge 303 filled with activated carbons, and anionic and cationic resins, which bind to and thereby remove contaminants.").

Appellant has not persuasively shown that a person of ordinary skill in the art would not have considered Rosenfeld's filtered milk product to be "substantially free of" environmental contaminants, especially in view of the Specification's lack of any particular level of contaminants that are unacceptable in the claimed product.

Finally, Appellant argues that "neither [Elimination] Diet nor Ianelli discloses a milk product that is 'substantially free of . . . known food allergens' as the claim requires. Though both disclose the general concept of

reducing any single food allergen, claim 1 requires the product to be 'substantially free' of several specified allergens." Appeal Br. 18.

As discussed above, however, the Markush language of claim 1 ("a food selected from the group consisting of") means that the claimed product may be substantially free of only *one* of the recited food allergens. And, as Appellant has conceded, the cited references "disclose the general concept of reducing any single food allergen." Appeal Br. 18. Appellant's argument is based on an interpretation of the claim language that is narrower than the broadest reasonable interpretation, and is therefore unpersuasive.

For the reasons discussed above, we affirm the rejection of claim 1 under 35 U.S.C. § 103 based on Evans, Boquien, Moller, Rosenfeld, Elimination Diet, and Iannelli. Claims 3–7, 9, and 10 fall with claim 1 because they were not argued separately. 37 C.F.R. § 41.37(c)(1)(iv) (2022).

Eligibility

Claims 1, 3–7, 9, and 10 stand rejected as being directed to a natural product and therefore ineligible for patenting. The Examiner finds that "[t]he naturally occurring counterpart of the claimed human milk product comprising (a) a human milk protein, (b) a human lipid, and (c) human polysaccharide would be human breast milk." Final Action 4.

The Examiner finds that the claimed "human milk product is produced by the method . . . which utilizes human mammary cells to secrete human milk product in vitro," and reasons that, "[s]ince the mammary cells cultured . . . are the same mammary cells present in nature, the molecules secreted by the cultured mammary cells are expected to be the same as those secreted by mammary cells in vivo." *Id.*

The Examiner finds that "the naturally occurring counterpart, i.e. human breast milk, would necessarily [be] free of culture medium." *Id.* at 5. The Examiner also finds:

> Regarding environmental contaminants or known food allergens, the naturally occurring counterpart would not contain any of these contaminants. It is noted that human breast milk contains low but measurable concentrations of environmental contaminants according to the instant specification. . . . However, these "environmental contaminants" are considered as non-natural and it is due to the intake of contaminants from industry and manufacturing products widely spread in the environment. Thus, these contaminants are non-natural and the natural human breast milk should not contain any of these environmental contaminants. It is the same for the claimed food allergens. Thus, "naturally occurring" human breast milk is considered to be free of any environmental contaminants or known food allergens.

Id.

Finally, the Examiner finds that "the claimed product being sterile would not change the characteristics of the claimed product different from the naturally occurring milk product. The naturally occurring milk product is considered to be sterile . . . until any contamination, and even such contamination would not change the characteristics of the product in a way rendering them significantly more than the judicial exception." *Id.* at 6. The Examiner concludes that "the isolated human milk components by the human mammary cells as claimed are considered not significantly different from the naturally occurring human breast milk secreted by mammary cells in mammary gland in vivo." *Id.*

The Examiner finds that the "judicial exception is not integrated into a practical application because the claims do not disclose any other elements

that integrate the judicial exception into a practical application," and "[t]he claim(s) does/do not include additional elements that are sufficient to amount to significantly more than the judicial exception." *Id.* at 7. The Examiner concludes that "the claimed isolated milk product is not an eligible subject matter under 35 USC § 101." *Id.*

Appellant argues that "the claimed isolated human milk product differs from naturally occurring human breastmilk in three important ways: (1) naturally occurring breast milk is not sterile; (2) naturally occurring breast milk is not free from known food allergens; and (3) naturally occurring breast milk is not free of environmental contaminants." Appeal Br. 9.

Principles of Law

Under 35 U.S.C. § 101, an invention is patent-eligible if it claims a "new and useful process, machine, manufacture, or composition of matter." 35 U.S.C. § 101. The Supreme Court, however, has carved out exceptions to what would otherwise appear to be within the literal scope of § 101; e.g., "[l]aws of nature [and] natural phenomena" such as products of nature, which are considered "building blocks of human ingenuity." *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014) (internal quotations omitted) (citing *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 590 (2013) and *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 89 (2012)). "[T]he 'manifestations of laws of nature' are 'part of the storehouse of knowledge,' 'free to all men and reserved exclusively to none.'" Manual of Patent Examining Procedure ("MPEP") § 2106.04(b)(I) (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130

(1948)). "When a law of nature or natural phenomenon is claimed as a physical product, the courts have often referred to the exception as a 'product of nature.'" MPEP § 2106.04(b)(II).

The Supreme Court has established a two-step framework for "distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Alice*, 573 U.S. at 217. "First, we determine whether the claims at issue are directed to" a patent-ineligible concept. *Id.* If so, "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." *Id.* (quoting *Mayo*, 566 U.S. at 78–79).

In 2019, the PTO issued guidance indicating how the Office's personnel would analyze patent eligibility under the Supreme Court's two-step framework. 2019 Revised Patent Subject Matter Eligibility Guidance ("Guidance"), 84 Fed. Reg. 50–57 (January 7, 2019).[12]

Under the Guidance, to determine what a claim is "directed to," we first look to whether the claim recites any judicial exceptions, including laws of nature, natural phenomena, and/or abstract ideas. Guidance, 84 Fed. Reg. at 53–54 ("Step 2A, Prong One"). If it does, we then look to whether the claim recites additional elements that integrate the recited judicial exception into a practical application. *Id.* at 54–55 (citing MPEP § 2106.05(a)–(c), (e)–(h)) ("Step 2A, Prong Two").

[12] The Office issued further guidance on October 17, 2019, clarifying the Guidance. USPTO, October 2019 Update: Subject Matter Eligibility (the "October 2019 Update"), available at https://www.uspto.gov/PatentEligibility.

If a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application—i.e., it is "directed to" a judicial exception—we then look to whether the claim contains an "'inventive concept' sufficient to 'transform'" the claimed judicial exception into a patent-eligible application of the judicial exception. Guidance, 84 Fed. Reg. at 56; *see also Alice*, 573 U.S. at 221 (quoting *Mayo*, 566 U.S. at 82).

Claims alleged to be patent-ineligible because they recite products of nature are properly analyzed under this framework. *See* Guidance, 84 Fed. Reg. at 54 n.20 ("This notice does not change the type of claim limitations that are considered to recite a law of nature or natural phenomenon . . . , including products of nature, see MPEP 2106.04(b) and (c).").

Analysis

Appellant's claim 1 recites a "nutritional human milk product," which is a composition of matter under 35 U.S.C. § 101. However, we must consider (Guidance, Step 2A, Prong One) whether it recites a judicial exception to § 101, i.e., whether it sets forth or describes a product of nature in accordance with the guidance in MPEP § 2106.04(b) and (c). Guidance, 84 Fed. Reg. at 54; October 2019 Update.

The Examiner finds that claim 1 recites a product of nature because "[e]ach component of the human milk product as claimed [i.e., protein, lipid, and polysaccharide] is naturally occurring product," and all of those components are found in human breast milk. Final Action 4. We agree. *See, e.g.*, Appellant's Spec. ¶ 25 ("Natural milk contains many other macronutrients, including proteins, lipids, polysaccharides and lactose.").

Appellant's claim 1 requires the milk product to be free of cell culture medium, but that does not distinguish it from naturally occurring breast milk, which is not produced in cell culture and therefore is inherently free of cell culture medium.

Claim 1 also requires the claimed product to be substantially free of "known food allergens derived from a food selected from the group consisting of: egg, fish, shellfish, tree nuts, peanuts, wheat, and soybean." Appeal Br. 20 (Claims App.). As previously discussed, the Markush claim language allows for the substantial absence of allergens from only one of the recited group of foods. And, as the Examiner reasonably found, "women who are not on diet of food allergen should not produce breastmilk containing food allergens." Ans. 16.

Thus, breast milk from a woman who was, for example, a vegetarian would inherently be free from fish or shellfish allergens. And breast milk from a woman who avoided gluten would inherently be free of wheat allergens. The "food allergens" limitation of claim 1 therefore does not distinguish the claimed product from naturally occurring breast milk.

Claim 1 additionally requires the claimed product to be substantially free of "environmental contaminants." Appeal Br. 20 (Claims App.). Neither the claim nor the Specification defines the term "substantially free of" nor do they recite specific environmental contaminants that are excluded from the claimed product. Appellant's Specification states that "[b]reast milk contains low but measurable concentrations of environmental

contaminants. . . . Environmental contaminants are partly secreted in breast milk." Spec. ¶ 135. The Specification also states:

> In some embodiments, the cultured milk product does not comprise or is substantially free of one or more environmental contaminants. In some embodiments, the cultured milk product does not comprise or is substantially free of persistent organic pollutants (POPs). In some embodiments, the cultured milk product does not comprise or is substantially free of polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), polychlorinated biphenyls (PCBs) and pesticides such as DDT.

Id. ¶ 136.[13]

Appellant has not, however, pointed to evidence in the record showing that contamination of human breastmilk is either ubiquitous or widespread. The Examiner, by contrast, cites Hassan[14] as evidence that "not all human breastmilk is contaminated with these pollutants, and thus, it is concluded that 'naturally occurring' breastmilk should be considered free of environmental pollutants." Ans. 16. Specifically, the Examiner points to Hassan's disclosure that "only 17.9% of test samples of human breastmilk was detected with DDE, which is one of persistent organic pollutants

[13] The Specification distinguishes between "environmental contaminants" like the ones specified in paragraph 136, and "[h]eavy metals . . . [that] also have bioaccumulative features known to accumulate in human milk." *Id.* ¶ 137. "In some embodiments, the cultured milk product does not comprise or is substantially free of one or more heavy metals," *id.* ¶ 138, but this limitation is not recited in the claims on appeal.

[14] H.E. Hassan et al., "Persistent Organic Pollutants in Human Milk: Exposure Levels and Determinants among Lactating Mothers in Lebanon," Journal of Food Protection 85(3):384–389 (2022). A copy of Hassan is included with this opinion.

(POPs)," and "DDT, another POP claimed in claim 5, and its derivative DOD were found in 22% of samples." *Id.*

A preponderance of the evidence of record supports the Examiner's position rather than Appellant's. Hassan states that "[t]he objective of [its] study was to assess the prevalence of POPs [persistent organic pollutants] in human milk collected from lactating mothers in Lebanon and to investigate the sociodemographic, nutritional, and other lifestyle determinants." Hassan 384, Abstr. Hassan discloses that, "[a]mong the screened POPs (hexachlorobenzene, PCB 18, lindane, β-BHC, heptachlor, PCB 31, PCB 28, PCB 52, DDE, dieldrin, PCB 118, PCB 149, PCB 153 plus endrin, DDD, DDT plus PCB 138, PCB 180, and PCB 194), DDE was the only POP detected in breast milk samples." *Id.* at 386, right col. Specifically, "DDE contamination was found in 17.9% of the breast milk sample[s]." *Id.* at 387, left col.

Hassan states that "[t]his lack of POPs can be attributed to the fact that Lebanon is not an industrialized country. [An earlier reference] also reported that POPs were significantly less prevalent in the Southern Hemisphere, where fewer industrialized countries are located." *Id.* at 386–387. Hassan thus provides evidence that breastmilk free of POPs—including PCBs, DDT, and DDE—is relatively common, at least in areas where industrialization is limited.

Appellant points out that the instant application "claims priority to December 10, 2020." Reply Br. 8, fn. 2. Appellant argues that "Hassan is not prior art to the claims here." *Id.* at 11. This argument is unpersuasive, because the Examiner cites Hassan only as evidence of the properties of

breastmilk, not as evidence that the claimed invention is anticipated or would have been obvious to those of ordinary skill in the art. *See In re Wilson*, 311 F.2d 266, 268–269 (CCPA 1962) ("The DuPont publication, the date of which is later than appellants' filing date, was cited by the examiner. . . . The board considered that the publication was properly cited to show a state of fact. After reading the entire publication, so do we. . . . As evidence of the characteristics of prior art foam products, however, we know of no reason in law why it is not acceptable.").

Appellant also argues that Hassan's evidence "that some human breast milk samples do not contain one or two types of one subset of environmental contaminant does not disclose a sterile, naturally occurring human breast milk product that is 'substantially free' of environmental contaminants." Reply Br. 11. Appellant points out that "[t]he specification discloses that the environmental contaminants recited in claim 1 can include POPs. . . . Heavy metals like lead, arsenic, cadmium and zinc are also environmental contaminants as recited in the claims." *Id.* at 11–12.

This argument is unpersuasive. POPs are precisely the environmental contaminants that Hassan tested for, and Hassan discloses that only one (DDE) was found in breastmilk, and even that was only found in 17.9% of the samples. Appellant has not cited contrary evidence showing that POPs are ubiquitous or even widespread contaminants of breastmilk.

We disagree with Appellant's position that the "environmental contaminants" recited in the claims include heavy metals. Appellant's Specification addresses environmental contaminants in its paragraphs 135 and 136, stating that "[i]n some embodiments, the cultured milk product

does not comprise or is substantially free of one or more environmental contaminants," and naming POPs, PCDDs, PCDFs, PCBs, and pesticides such as DDT as examples.

The Specification then states that "[h]eavy metals . . . *also* have bioaccumulative features known to accumulate in human milk." *Id.* ¶ 137. The Specification states that ""[i]n some embodiments, the cultured milk product does not comprise or is substantially free of one or more heavy metals." *Id.* ¶ 138. Appellant has not pointed to any definition of "environmental contaminant" or any other disclosure in the Specification supporting the position that "environmental contaminants" include heavy metals.

In short, a preponderance of the evidence of record supports the Examiner's position that human milk substantially free of environmental contaminants is naturally occurring.

Finally, claim 1 requires the claimed product to be sterile. Appellant argues that, "unlike the claimed milk product, 'naturally occurring breast milk is not sterile. It contains a microbiome of commensal and probiotic bacterial strains, such as lactic acid bacteria and bifidobacteria[].'" Appeal Br. 9 (quoting the Bionaz Decl.[15]). Appellant argues:

> As described by Dr. Bionaz, the presence of a microbiome in naturally occurring milk results in several characteristics that would necessarily be different from the claimed sterile milk. The milk microbiome seeds the infant's developing microbiome with beneficial bacteria. The microbiome bacteria and their metabolites have bioactive

[15] Declaration under 37 C.F.R. § 1.132 of Massimo Bionaz, dated April 27, 2022.

> properties. For example, the milk microbiome promotes mother and infant health by preventing or treating of lactational mastitis. The milk microbiome is involved in the biosynthesis of antimicrobial compounds, for example in pathogenic Salmonella infection by suppressing the release of IL-8 to protect the infant intestine against epithelial cell damage by the Salmonella.

Id. at 10.

Appellant also cites the O'Brien Declaration[16] as stating that "[n]aturally occurring human milk comprises microbes and its own living microbiome," and cites the Koivusaari Declaration as stating that the claimed sterile milk product "is only possible due to recent cell culturing advances enabling an aseptic, closed production process." *Id.* at 9.

Appellant argues that "bacteria and contaminants result in spoilage of naturally occurring breastmilk. This is in stark contrast to the claimed milk product that is 'sterile and thus shelf-stable.'" *Id.* at 11 (quoting the O'Brien Decl.). Appellant argues that it "submitted testimony from an expert in nutrigenomics and lactation biology that the 'sterility of the claimed milk product meaningfully changes the properties of the claimed milk product as compared to naturally occurring milk.'" *Id.* (quoting the O'Brien Decl.). Appellant concludes that "the sterility, and therefore shelf stable quality, of the claimed product is a marked difference from naturally occurring breastmilk." *Id.* at 11–12.

The Examiner "acknowledge[s] that human breast milk when collected from a lactating woman typically contains microorganisms or a

[16] Declaration under 37 C.F.R. § 1.132 of Claire O'Brien, dated August 30, 2022.

microbiome." Ans. 13. The Examiner reasons that "microorganisms . . . are not an original component of human breast milk produced and secreted from the mammary epithelial cells. Rather the human breast milk is produced and secreted from mammary epithelial cells as sterile and stored in alveoli of the mammary gland." *Id.* at 14.

In other words, the Examiner interprets claim 1 as reading on human milk before it is expressed from the breast, while it is still inside a woman's body. Claim 1, however, is directed to "[a]n *isolated* nutritional human milk product." Claim 1 (emphasis added). "[H]uman breast milk . . . stored in alveoli of the mammary gland," Ans. 14, is not an isolated product. The Examiner's interpretation is therefore unreasonably broad.

The Examiner also cites Huang[17] as evidence that "several studies have found that some breast milk is extremely low in bacteria or is even sterile . . . and bacteria were detected only in 11 breast milk samples out of 17 samples, and the other 6 samples were sterile." Ans. 14.

Huang discloses that "[s]everal studies have found that some breast milk is extremely low in bacteria or is even sterile." Huang 1, Abstr. Huang teaches that "[t]he purpose of [its] study was to investigate the gut microbiota of infants fed with bacterial milk or sterile milk." *Id.*

"A total of 17 healthy pregnant women and 17 infants were enrolled in [Huang's] study." *Id.* Huang states that "[b]acteria were detected in 11 breast milk samples and the bacterial detection rate was 64.7%." *Id.* Huang

[17] T. Huang et al., "Effect of breast milk with or without bacteria on infant gut microbiota," BMC Pregnancy and Childbirth 22:595– (2022), https://doi.org/10.1186/s12884-022-04930-6, pp. 1–11.

"found some breast milk collected from healthy women does not contain any microbial community." *Id.* at 7, left col. The Examiner thus has presented evidence that more than one-third of human milk samples were found to lack detectable bacteria.

Appellant has presented evidence to the contrary. Dr. Bionaz states that "[n]aturally occurring breast milk is not sterile. It contains a microbiome of commensal and probiotic bacterial strains. . . . The bacterial strains are present when milk is collected from the breast under sterile conditions." Bionaz Decl. ¶ 4. Dr. Bionaz also states that

> naturally occurring milk is not a sterile product, but a living product with an active microbiome. . . . The pending claims require that the milk product be sterile, unlike naturally occurring milk. Further, the sterility of the claimed milk product meaningfully changes the properties of the claimed milk product as compared to naturally occurring milk.

Id. ¶ 6.

Similarly, Dr. O'Brien states that "[n]aturally occurring human milk comprises microbes and its own living microbiome." O'Brien Decl. ¶ 10. Dr. O'Brien also states that "[n]atural milk is not shelf-stable," but "[s]terile milk is shelf-stable." *Id.* ¶¶ 10–11. Dr. O'Brien concludes that "[t]he claims of the subject application are directed to a milk product that is sterile and thus shelf-stable. Accordingly, the pending claims do not cover a naturally occurring product." *Id.* ¶ 11.

On balance, we cannot say that a preponderance of the evidence supports a finding that sterile human milk—which is also substantially free of environmental contaminants and at least one of the specified food allergens—is not naturally occurring. But, even if sterile human milk does

not occur naturally, the issue that then arises is whether the absence of naturally occurring bacteria from the claimed milk product makes it markedly different from natural human milk.

We conclude that it does not. The U.S. Supreme Court held that "Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 590 (2013). That is, "Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention." *Id.* at 591. "Nor are Myriad's claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule." *Id.* at 593.

Similarly here, Appellant did not create human milk comprising a protein, a lipid, and a polysaccharide, or even human milk substantially free of environmental contaminants and at least one known food allergen. These components and conditions of human milk existed in nature before Appellant produced human milk in vitro or ex vivo.

To be sure, Appellant has disclosed a method of making human milk that, by virtue of the method by which it is made, is necessarily free of certain components that may occur in some human milk produced by lactating women. But the evidence shows that most of the limitations of claim 1 are met by at least some naturally occurring human milk, and just as separating the BRCA1 gene from its surrounding genetic material was held

not to be an act of invention, *Myriad*, 569 U.S. at 591, separating or killing the bacteria normally found in naturally occurring human milk from the other components of the milk is not enough to confer "markedly different characteristics" on the claimed product. *See Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

The *Myriad* Court held that "genes. . . are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material." *Myriad*, 569 U.S. at 596. The same principle applies here as well: human milk is not patent eligible under § 101 simply because it has been separated from the live bacteria that are naturally present in it.

To complete the Office's analysis, we next look to whether the claim recites additional elements that integrate the recited judicial exception into a practical application. 84 Fed. Reg. at 54–55 (citing MPEP § 2106.05(a)–(c), (e)–(h)) ("Step 2A, Prong Two"). Here, however, claim 1 does not recite any additional elements beyond the human milk product that is not markedly different from naturally occurring human milk and, thus, claim 1 does not integrate the claimed product into a practical application of the natural product.

Finally, we look to whether the claim contains an "'inventive concept' sufficient to 'transform'" the claimed judicial exception into a patent-eligible application of the judicial exception. Guidance, 84 Fed. Reg. at 56. The Guidance states that examiners should "evaluate the additional elements individually and in combination under Step 2B to determine whether they provide an inventive concept (i.e., whether the additional elements amount to significantly more than the exception itself)." *Id.*

As discussed in reference to Step 2A, Prong Two, however, claim 1 lacks any additional elements beyond the product of nature itself. Claim 1 therefore lacks additional elements that amount to significantly more than the exception itself.

For the reasons discussed above, we affirm the rejection of claim 1 under 35 U.S.C. § 101. Claims 3–7, 9, and 10 fall with claim 1 because they were not separately argued. 37 C.F.R. § 41.37(c)(1)(iv) (2022).

DECISION SUMMARY

The following table summarizes our decision:

Claim(s) Rejected	**35 U.S.C. §**	**Reference(s)/Basis**	**Affirmed**	**Reversed**
1, 3–7, 9, 10	101	Eligibility	1, 3–7, 9, 10	
1, 3–7, 9, 10	103	Evans, Boquien, Moller, Rosenfeld, Elimination Diet, Iannelli	1, 3–7, 9, 10	
Overall Outcome			1, 3–7, 9, 10	

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). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED