No.

In the Supreme Court of the United States

URVASHI BHAGAT,

Petitioner,

v.

ANDREI IANCU, DIRECTOR, U.S. PATENT AND TRADEMARK OFFICE,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

This petition presents a conflict between the incentive to invent, as the Constitution provides for, and the breadth of patent-eligible subject matter under 35 U.S.C. § 101. It has become difficult to recognize the line between patentable subject matter and non-patentable products of nature. This Court has made conflicting statements regarding that line.

In the case at hand, petitioner, a solo inventor, has invented new and useful lipid compositions that can improve the health of millions of Americans who suffer from chronic illness. Yet she is being denied a patent that would support her in bringing these beneficial inventions to market. This frustrates the purpose of the U.S. patent system.

This petition further presents the issue of holding the federal courts accountable in properly reviewing agency decisions.

The Questions Presented are:

1. a. Whether the Federal Circuit erred in finding petitioner's patent application claims unpatentable under 35 U.S.C. § 101 because the court failed to apply the correct patent-eligibility standard under this Court's conflicting holdings in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948) and *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

b. Whether the Federal Circuit erred in finding petitioner's patent application claims unpatentable under 35 U.S.C. § 101 because the court did not apply the patent-eligibility standard set forth in *Myriad*.

2. Whether the Federal Circuit erred in affirming the USPTO's decisions under 35 U.S.C. §§ 101 and 102(b) because it failed to apply "meaningful review" to that decision, as required by the Administrative Procedure Act.

CORPORATE DISCLOSURE STATEMENT

Asha Nutrition Sciences, Inc. owns 100% of U.S. Patent Application No. 12/426,034, the patent application at issue. Asha Nutrition Sciences, Inc. has no parent company, and no publicly held corporation owns 10% or more of its stock. Petitioner Urvashi Bhagat is the applicant in the '034 application and is president of Asha Nutrition Sciences, Inc.

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JURISDICTION

The court of appeals issued its decision on March 16, 2018. A combined petition for panel rehearing and rehearing en banc was denied on June 1, 2018. Pet.App. 64a-65a. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

1. 35 U.S.C. § 101 provides: "Inventions patentable. Whoever 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, subject to the conditions and requirements of this title."[1]

2. 35 U.S.C. § 102(b) provides:

> A person shall be entitled to a patent unless—
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> . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.[2]

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[1] 35 U.S.C. § 101 did not change under the Leahy-Smith America Invents Act (2011) ("AIA").

[2] The pre-AIA version of 35 U.S.C. § 102(b), set forth in the

STATEMENT

This case presents an instance in which an inventor has made and disclosed valuable inventions that apply new and useful discoveries to the solving of long-felt and critical public health problems. Chronic diseases affect millions of Americans. Petitioner, the inventor of U.S. Patent Application 12/426,034 (which claims priority to an April 21, 2008 filing date), has developed formulations that have the potential to ameliorate or alleviate the symptoms of many who suffer from chronic diseases. Nevertheless, petitioner has been denied the patent reward that this country's founders enabled to encourage and foster innovation.

The rejection of the claims pending in the '034 application, at issue here, appears to be, in part, a consequence of uncertainty in the proper application of 35 U.S.C. § 101. This case merits review to clarify the scope of patentable subject matter under 35 U.S.C. § 101 and of the incentive to innovate and to invest in and disclose innovations. Review of this case will also resolve some of the substantial doubt that uncertainty surrounding § 101 has cast on the validity and value of such patents.

Under the Court's interpretation of 35 U.S.C. § 101, "anything under the sun that is made by man" is eligible for patenting, provided that it meets other statutory requirements. *See Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). The Court has determined that patentable subject matter does not include physical phenomena, laws of nature, and

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text, applies to this case.

abstract ideas. *See id.* The question of what falls within the category of physical phenomena, also referred to as "natural phenomena," remains difficult to answer. *See*, *e.g.*, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589-90 (2013). Petitioner seeks clarification from the Court on this issue.

A. Background

In this case, petitioner Urvashi Bhagat, motivated by the illness, suffering and premature death of her own mother, devoted herself to researching the relationship between diet and chronic illness. She focused on the role of lipids in health and disease. Lipids are a diverse class of over 100 distinct chemical compounds that are ubiquitous in nature and include, for example, fatty acids, cholesterol, steroids and certain vitamins. *See* Eoin Fahy *et al.*, *A comprehensive classification system for lipids*, 46 J. Lipid Res. 839, 843, 848-50, 854-55 (2005) (listing and describing classes of lipids). Lipids play many important biological roles, including being crucial cell membrane components, providing a source of energy to the organism, affecting protein function and involvement in gene regulation. *See id.* at 848, 850, 854-55; *see also* Fed. Cir. App. Appx0056. Lipids affect the activity of each other and their derivatives function as important hormones and chemical messengers that affect a broad range of physiological functions. *See* Fed. Cir. App. Appx0056.

Petitioner's research has focused on two subsets of lipids, the omega-6 and omega-3 families of fatty acids. Fed. Cir. App. Appx0056-Appx0057. Linoleic

acid (LA) is the precursor of the omega-6 family, and alpha-linolenic acid (ALA) is the precursor of the omega-3 family. *Id.* The bodies of mammals, including humans, cannot synthesize LA and ALA, but can synthesize the other omega-6 and omega-3 fatty acids from dietary LA and ALA. *Id.* Mammals must obtain LA and ALA from dietary sources. *Id.*

From about 1930 to about 1960, nutritional studies demonstrated that omega-6 fatty acids were active in growth and maintenance of skin health. Between 1964 and 1979, researchers developed awareness that arachidonic acid (AA) (an omega-6 fatty acid) metabolizes into prostaglandins and leukotrienes, involved in several disease processes associated with arthritis, asthma, atherosclerosis, thrombosis, tumor proliferation, and a variety of immune-inflammatory disorders. Therefore, high amounts of omega-6 were believed to promote pathophysiology. Ingestion of about 1% of daily calories as LA was considered to be optimal, and omega-3 fatty acids were believed to be beneficial and inhibit omega-6 activity by competitive metabolism. *See* Fed. Cir. App. Appx4263-Appx4269.

Experts believed that, for LA and ALA to be equally competitive, their intake should be in the ratio of 14:1, but that equality of competition may not be the criterion for optimal function. *See*, *e.g.*, Fed. Cir. App. Appx0231. The nutrition field recommended very low levels of omega-6 consumption. *See*, *e.g.*, *id.* Appx4448 (indicating upper limit of omega-6:omega-3 ratio of 2.32:1 and maximum omega-6 intake of 6.67 grams/day for a 2000 kcal diet). Thirty scientists ratified the

recommendation. *See id.* Appx4448-Appx4449.

Petitioner recognized, through her research in the early to mid-2000s on people who suffered from certain chronic conditions, that the recommended dosages and ratios were too low and that the prior art had greatly misunderstood the dose-effect of omega-6 fatty acids. The prior art held that a stepwise increase in omega-6 intake is associated with adverse health, such as an increase in tumorigenesis when the intake is in the range of 0.5-4.4% of calories. *See* Clement Ip *et al., Requirement of Essential Fatty Acid for Mammary Tumorigenesis in the Rat*, 45 Cancer Res. 1997-2001 (1985). Those skilled in the art therefore were not motivated to practice higher dosages of omega-6. *See* Fed. Cir. App. Appx4263-Appx4269 and Appx4446-Appx4449. Petitioner found, however, that higher intake of omega-6 was required to overcome adverse health conditions (for example, at least 11 grams per day or at least 5.82% of calories consumed). *See* Fed. Cir. App. Appx0082-Appx0087, Appx0089-Appx0090, Appx0092, Appx0093, Appx0096-Appx0097 and at Appx0083-Appx0085 (Table 20).

Petitioner also discovered that the deficiency of omega-6 potentiates certain mechanisms, such that sudden increases in omega-6 have an overflow effect, which can lead to myocardial infarction, strokes, infections, and physiological disturbances. *See* Fed. Cir. App. Appx0082-Appx0097 and Appx1346-Appx1347.

Petitioner also determined that the optimal amounts and ratios of omega-6 and omega-3 intake depend upon a subject's intake of other lipids such

as, for example, antioxidants, phytochemicals, and other fatty acids and on a subject's demographics. *See*, *e.g.*, *id.* Appx0057-Appx0058, Appx0060-Appx0061. She devised formulations that embodied these ratios and amounts, and has pursued patents directed to such formulations. "[T]he ratio between [omega]-6-to-[omega]-3 of 15–17:1 in diets is not the problem, the problem is the other factors that influence the metabolism of [omega]-6 and [omega]-3." *See id.* Appx7367.

Petitioner's claimed formulations, being mixtures of components from different sources, are formulated to provide certain amounts and ratios of certain components. At the same time, other components that are not desirable in large amounts or high concentrations become diluted as a consequence of mixing lipids from different sources. The formulations thus provide a dual advantage.

Subsequent to petitioner's research and patent application filings, several public health organizations advised higher omega-6 intake based on experimental results. For example, the American Heart Association advised that the consumption of at least 5% to 10% of energy from omega-6 polyunsaturated fatty acids reduces the risk of chronic heart disease relative to lower intakes. *See* Fed. Cir. App. at Appx0205-Appx0207, Appx4222-Appx4234. Other "results suggested that low concentrations (≤200 μM) of LA promote colorectal cancer cell growth, while high levels (≥200 μM) induce apoptosis of the colorectal cancer cells *in vitro*." *Id.* at Appx4291.

Therefore, prior to petitioner's invention of the

claimed lipid formulations, the person of ordinary skill in the art *could not have determined* and practiced the claimed suitable ratios and dosages of total omega-6 and omega-3 fatty acids for a subject. Those of ordinary skill in the art have testified to this effect. *See* Fed. Cir. App. Appx3860-3861, Appx3868-3869, Appx3850. Additionally, the public cannot solve this problem because lipids are unpredictable in their sources and less than 1% of Americans understand lipids. *See id.* Appx5703, Appx5472-5474, Appx6650-6668, Appx6670-6685, Appx7910. Thus the claimed subject matter is directed to solving a poorly understood problem and meeting a critical and long-felt, unmet need. It has great potential to protect and improve public health. *See id.* Appx6492-Appx6493, Appx6509-Appx6510, Appx6526-Appx6527.

B. Facts and procedural history

Petitioner filed U.S. Patent Application No. 12/426,034, the application at issue in this case, on April 17, 2009. *See* Fed. Cir. App. Appx0056-Appx0114. The '034 application claimed priority to three provisional applications, U.S. Provisional Nos. 61/046,747, filed April 21, 2008, 61/075,708, filed June 25, 2008, and 61/111,593, filed November 5, 2008. *Id.* Appx0056. Prosecution of the '034 application culminated in a final office action dated September 22, 2015. Claims 52, 61, 64, 65, 67-69, 73-75, 77, 78, 80, 82, 83, 90-105, 107-109, 111, 113-122, and 124-145 were then pending, of which claims 65, 91, 129, and 130 were independent. The Examiner rejected all claims as either drawn to non-statutory subject matter under 35 U.S.C. § 101, anticipated under 35 U.S.C. § 102(b) (pre-AIA), or

both. Petitioner filed an amendment on September 30, 2015 to put the claims in better condition for appeal, amending only dependent claim 117.

Independent claim 65 is reproduced below. The four independent claims 65, 91, 129, and 130 and all dependent claims are reproduced in the Appendix. *See* Pet.App. 68a-90a.

> 65. A lipid-containing formulation, comprising a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4: 1 or greater, contained in one or more complementing casings providing controlled delivery of the formulation to a subject, wherein at least one casing comprises an intermixture of lipids from different sources, and wherein
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> (1) omega-6 fatty acids are 4-75% by weight of total lipids and omega-3 fatty acids are 0.1-30% by weight of total lipids; or
>
> (2) omega-6 fatty acids are not more than 40 grams.

Petitioner appealed *pro se* to the Patent Trial and Appeal Board. The Board issued its decision on April 15, 2016, affirming the Examiner's claim rejections. Pet.App. 23a-63a.

The Board relied on this Court's decisions in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948) and *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013) in finding the claims read on patent-ineligible "products of

nature." Pet.App. 31a-34a. The Board rejected Appellant's contention that the claimed subject matter was patent-eligible. Pet.App. 32a-37a.

Petitioner filed a request for rehearing by the Board on June 14, 2016. The Board denied the request on June 21, 2016. Pet.App. 21a-22a. Petitioner filed a petition for supervisory review by the Chief Administrative Patent Judge of the Board on July 5, 2016 and a Notice of Appeal *pro se* to the United States Court of Appeals for the Federal Circuit on August 16, 2016. The Board dismissed the petition for lack of jurisdiction on September 30, 2016. *Id.* 15a-20a.

The Federal Circuit issued a non-precedential decision on March 16, 2018, affirming the Board's decision. *Id.* 1a-14a. The Federal Circuit had jurisdiction under 35 U.S.C. § 141(a). The court concluded substantial evidence supported the Board's conclusion "that the claims are directed to the omega-6 and omega-3 fatty acids that occur in nature and that the asserted claim limitations do not distinguish the claimed products and compositions from those shown in the cited references." Pet.App. 14a. The court also affirmed the Board's findings on anticipation. *Id.* 10a.

The court denied petitioner's petition for panel rehearing and for rehearing en banc on June 1, 2018. *Id.* 64a-65a.

REASONS FOR GRANTING THE PETITION

This case is an ideal vehicle for providing the clarification the patent and investment community require. At issue is how to determine whether

something is a product of nature under 35 U.S.C. § 101. This case embodies the need for further guidance because this application was rejected while patents that contain claims indistinguishable, on § 101 grounds, from the present case have issued previously (*see infra*). Clarification from the Court will enable the patent and investment communities to allocate their resources more efficiently by pursuing patents only on patent-eligible subject matter.

More specifically, the patent community and others lack a clear understanding of the boundaries of § 101 and how the statute is properly applied under *Funk Bros.* and *Myriad*, including within the life sciences generally. *See*, *e.g.*, Peter Lee, *The Supreme Court's* Myriad *Effects on Scientific Research: Definitional Fluidity and the Legal Construction of Nature*, 5 U.C. Irvine L. Rev. 1077, 1104-1110 (2015). Also, § 101 challenges have increased subsequent to the Court's series of § 101 decisions. According to one analysis, in the art unit in which the '034 application was prosecuted, the percentage of USPTO rejections that cite § 101 has almost tripled from the pre-*Bilski* period (just over 5%) to the post-*Alice* period (just under 15%).[3] *See* James Cosgrove, § 101 Rejections in the Post-Alice Era (March 7, 2017) (available at https://www.ipwatchdog.com/2017/03/07/101-rejections-post-alice-era/id=78635/ (last visited Aug. 27, 2018)).

The patent system promotes "progress by offering

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[3] *See Bilski v. Kappos*, 561 U.S. 593 (2009), *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014)

inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts." *See Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980); *see also In re Piasecki*, 745 F.2d 1468 (Fed. Cir. 1984) ("it states that advancement in the art is the overriding constitutional standard 'to be implemented by the Commissioner and the courts'"[4]). Congress has provided a patent system to "have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens." *Chakrabarty*, 447 U.S. at 307 (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974)).

The current uncertainty in the patent community has a chilling effect, deterring the investment of work and resources in innovation when recoupment in the form of a patent is unclear. *See*, *e.g.*, Sen. Christopher Coons, *A Few Thoughts on the Supreme Court's Section 101 Jurisprudence* (2017) (available at http://www.ipwatchdog.com/2017/02/08/ thoughts-supreme-courts-section-101-jurisprudence/ id=78166/) (last visited Aug. 16, 2018) (discussing "the sheer amount of ambiguity that the developing Section 101 jurisprudence is creating"). Additional guidance will provide confidence in, and thereby promote, such investment. The public will benefit from the inducement to innovate. Particularly in this case, patent protection is necessary to nurture this innovation because it cannot be heard above the

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[4] Referring to *Comm'r of Patents v. Deutsche Gold-und-Silber-Scheideanstalt Vormals Roessler*, 397 F.2d 656, 665 (D.C. Cir. 1968).

noise.

Also at issue is a just outcome in the Federal Circuit that can only be obtained by meaningful review of the Board's decision.

A. *Myriad* and *Funk Bros.* articulate conflicting standards of patent-eligibility

1. 35 U.S.C. § 101

"Whoever 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, subject to the conditions and requirements of this title." 35 U.S.C. § 101 (2018).

This Court has construed "'manufacture' in § 101 in accordance with its dictionary definition to mean 'the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.'" *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (quoting *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931)). The Court further has endorsed construing "composition of matter" "to include 'all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids." *Id.* at 308. The Court has found that a "broad construction" of the patent laws conforms with Thomas Jefferson's vision and the history of the patent system generally. *See id.* at 308-09 (stating, in part, the Patent Act of 1793 "embodied Jefferson's

philosophy that 'ingenuity should receive a liberal encouragement'").

Section 101 nevertheless has limits. "The laws of nature, physical phenomena, and abstract ideas have been held not patentable." *Id.* at 309. For example, one may not patent "a new mineral discovered in the earth." *Id.* at 309.

2. Patent-eligibility under *Funk Bros.*

In *Funk Bros.*, the Court held not patent-eligible a mixture of different species of naturally-occurring bacteria. *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 128 n.1, 130, 132 (1948).

Each species of bacteria was useful in planting and growing a subset of crops, and each had been sold separately because each species inhibited the others. *See id.* at 128-130. The inventor discovered certain strains of each bacterium did not inhibit certain strains of the other species, and could "be isolated and used in mixed cultures." *Id.* at 130. The inventor patented combinations of the non-inhibitory bacteria that could be used together on all of the crops. *See id.* Thus, a single, multi-function combination bacterial culture replaced multiple, single-function cultures. The claimed mixture provided commercial advantages and convenience to farmers and agricultural suppliers. *Id.* at 131-132.

The Court reasoned that the qualities of the bacteria at issue were "manifestations of laws of nature, free to all men and reserved exclusively to none." *Id.* at 130. If "there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end." *Funk*

Bros., 333 U.S. at 130. Yet the "aggregation of species fell short of invention within the meaning of the patent statutes." *Id.* at 131. Although devising such a mixture represented a "discovery" and provided an "advantage," no species acquired a different use and each species had "the same effect it always had" and "perform[ed] in their natural way." *Id.* at 131. Once the patentee had discovered the non-inhibitive quality of the different strains, "the state of the art made the production of a mixed inoculant a simple step," and thus "was not the product of invention."

While the statutory precursor to the current § 101 governed both patent-eligibility and novelty at the time *Funk Bros.* was decided, the Court has treated this case as a patent-eligibility case that contributes to defining the contours of the modern § 101. *See, e.g.*, *Chakrabarty*, 447 U.S. at 310 (citing *Funk Bros.* in support of the proposition that § 101 has "limits").[5]

3. Patent-eligibility under *Myriad*

In *Myriad*, the Court held that "genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 596 (2013). On the other hand, cDNA is

[5] The statute at the time, titled "Inventions patentable," referred to obtaining a patent for invention or discovery of "any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvements thereof," that was, for example, "not known or used by others in this country, before his invention or discovery thereof." 35 U.S.C. § 31 (1946).

patent-eligible because it "is not naturally occurring." *Id.* at 594. Rather, cDNA is a synthetic partial copy of gene DNA that contains the same protein-encoding exons as the corresponding gene DNA but not the gene's non-coding introns. *See id.* at 594. "cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, cDNA is not a 'product of nature,'" with the exception of cDNA that corresponds to a stretch of DNA that contains no introns. *Id.* at 595.

At issue in *Myriad* were the BRCA1 and BRCA2 genes, mutations in which are associated with breast cancer. Specifically, the patentees had claimed isolated copies of the DNA corresponding to the genes, removed from the cell, and cDNAs that comprise the BRCA1 or BRCA2 exons spliced together, omitting the introns present in the naturally occurring genes. "Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes" or "create or alter the genetic structure of DNA," so patent claims to "naturally occurring, isolated DNA segments" were considered not sufficiently removed from the natural product. *Myriad*, 569 U.S. at 590. "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. Thus, simply discovering something in nature and isolating it does not qualify for patent-eligibility because it is not inventive.

In contrast, cDNA is patent-eligible because it is "something new" that "is not naturally occurring." *Myriad*, 569 U.S. at 594, 595. The Court reached

this conclusion despite the fact that preparing cDNA was routine at the time the patents at issue in *Myriad* were filed (*circa* 1994). *See*, *e.g.*, Benjamin Lewin, *Genes IV* 456 (1990) ("synthesiz[ing] a duplex DNA from an mRNA" "is especially easy for mRNAs that carry a poly(A) tail at the 3' end," from which can be prepared "a cDNA clone").

This conclusion, however, directly conflicts with *Funk Bros.*, which reasoned that a "simple step" that leads from the discovery to the claimed subject matter did *not* make the claimed subject matter "the product of invention" or patent-eligible. *See Funk Bros.*, 333 U.S. at 132.

Further, the information in cDNA is "dictated by nature," as the Court recognized. *See Myriad*, 569 U.S. at 595. In sum, no inventiveness was required to prepare BRCA1 or BRCA2 cDNA once the BRCA1 and BRCA2 genes were isolated.

The "rule against patents on naturally occurring things is not without limits" because "'all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,' and 'too broad an interpretation of this exclusionary principle could eviscerate patent law.'" *Id.* at 589-90 (quoting *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 566 U.S. 66, 71 (2012)). Thus, "patent protection strikes a delicate balance between creating 'incentives that lead to creation, invention, and discovery' and 'imped[ing] the flow of information that might permit, indeed spur, invention.'" *Myriad*, 569 U.S. at 590 (quoting *Mayo*, 566 U.S. at 92).

4. *Funk Bros.* and *Myriad* produce conflicting results

Funk Bros. and *Myriad* each provide guidance for determining whether, when a natural product is used to make a new product, the new product is sufficiently different from the natural product to be patent-eligible under section 101. The guidance each provides, however, yields conflicting results.

Myriad indicates that the new product, to be patent-eligible, cannot be identical to the natural product.

The application of *Myriad*'s reasoning to the facts in *Funk Bros.* leads to a different outcome than the Court reached in *Funk Bros.* Specifically, the Court would have recognized that the combinations of bacterial species at issue were in fact patent-eligible because such combinations represented the application of a discovery to yield "something new" that was "not naturally occurring," specifically, a mixture not found in nature of different bacterial species. *See Myriad*, 569 U.S. at 594, 595. The Court in *Funk Bros.* in fact recognized the bacterial combinations or mixtures provided "an important commercial advance." *Funk Bros.*, 333 U.S. at 132.

In *Funk*, the inventor discovered certain bacterial properties and applied this discovery to make a new and useful combination of natural products. In *Myriad*, the inventors discovered two BRCA genes and applied this discovery to make a new and useful product (cDNA). In both cases, the claimed subject matter functioned naturally (the cDNA in *Myriad* encodes the same genetic information as the genomic DNA and otherwise functions the same as naturally

occurring DNA). As Justice Frankfurter stated, the claimed combination of bacteria was a patentable "invention" because the claimed "mixture does in fact have the new property of multiservice applicability." *See Funk Bros.*, 333 U.S. at 135 (concurring on other grounds). Further, Justice Frankfurter considered the patent-eligibility of the claimed composite to have been validated by the majority's statement that "if there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end." *Id.* at 135.

Similarly, application of the reasoning in *Funk Bros.* to the facts of *Myriad* would lead to a finding that both Myriad's genomic DNA and the corresponding cDNA are not patent-eligible. In *Funk Bros.*, the Court reasoned that the inventor's discovery of the bacterial qualities underlying the invention was "no more than the discovery of some of the handiwork of nature," and therefore "is not patentable." *Funk Bros.*, 333 U.S. at 131. The inventor's application of that discovery to devise a combination of different bacteria species "is hardly more than an advance in the packaging of the inoculants." "[T]hat aggregation of species fell short of invention within the meaning of the patent statutes." *Id.* at 131.

Applying this reasoning to *Myriad*, the identification of the BRCA genes was a discovery of some of the "handiwork of nature," so those genes isolated from the genome would not be patent-eligible under *Funk Bros.* *Id.* at 131.

Further, cDNA prepared using the knowledge of the BRCA genes would not represent a patent-

eligible "invention or discovery," as *Funk Bros.* would require, because it was a "simple step" to prepare the claimed BRCA cDNAs from the corresponding genomic DNA. *See id.* at 132. In sum, no inventiveness was required to prepare BRCA1 or BRCA2 cDNA once these genes were isolated. Thus, the application of *Funk Bros.* to the facts in *Myriad* would have led to BRCA genomic *and cDNA* being held unpatentable.

B. The court below erred in finding petitioner's claimed formulations not patent-eligible

Myriad articulates the proper patent-eligibility standard under 35 U.S.C. § 101. The Board and Federal Circuit erred in finding the pending claims patent-ineligible under *Myriad* because they applied the wrong standard under 35 U.S.C. § 101.

1. Claim construction

Each element contained in a patent claim is deemed material to defining the scope of the patented invention. *See Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 29 (1997).

"A claim in an unexpired patent that will not expire before a final written decision is issued shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. 42.200(b). The Court has endorsed the Patent Office's adoption of the broadest reasonable construction standard. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2146 (2016). "While the broadest reasonable interpretation standard is broad, it does not give the [b]oard an unfettered license to interpret the words in a claim

without regard for the full claim language and the written description." *In re Power Integrations, Inc.*, 884 F.3d 1370, 1375 (Fed. Cir. 2018) (holding that the "board's claim construction here was unreasonably broad and improperly omitted any consideration of the disclosure in the specification").

"The ultimate issue of the proper construction of a claim should be treated as a question of law" but "subsidiary factfinding is sometimes necessary." *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 838 (2014) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 378, 388, 390 (1996). "[W]e review the Board's ultimate claim constructions de novo and its underlying factual determinations involving extrinsic evidence for substantial evidence." *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1297 (Fed. Cir. 2015) (citing *Teva*, 135 S. Ct. at 841-42 and "our review of Board determinations) (overruled on other grounds); *see also Dickinson v. Zurko*, 527 U.S. 150, 152, 161, 164 (1999) ("A reviewing court reviews an agency's reasoning to determine whether it is 'arbitrary' or 'capricious, or, if bound up with a record-based factual conclusion, to determine whether it is supported by 'substantial evidence.'"[6]).

Independent claims 65 and 91 and their dependent claims recite formulations that comprise "an intermixture of lipids from different sources." Pet.App. 69a, 73a. Independent claims 129 and 130 recite formulations that require "an intermixture of fatty acids from different sources." *Id.* 86a. The

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[6] The court set forth its reasoning in view of the Administrative Procedure Act, 5 U.S.C. § 706. Pet.App. 66a.

plain language of the claims thus requires a formulation that contains components that come from different sources. The '034 application instructs that "[i]n some embodiments, synergy among complementing nutrients from different sources may be incorporated. Furthermore, using different sources avoids concentrated delivery of specific phytochemicals that may be harmful in excess." Fed. Cir. App. Appx0062.

The specification indicates "sources" means seeds, nuts, fish, and other natural products, and oils derived therefrom. *See*, *e.g.*, Fed. Cir. App. Appx0061 (stating that "nuts and seeds" "are one of the richest sources of natural nutrients") and Appx0069 (describing compositions that "were made up of a variety of oils, nuts and seeds").

> (a) The decisions below incorrectly construed the claims as "product-by-process" claims, thereby improperly reading the limitation "intermixture . . . from different sources" out of the claims

The Board construed the claim term "intermixture" to refer to a process, and thus construed the claims as product-by-process claims not limited by the recited process. Consequently, it considered any single-source composition, such as walnut oil alone, to read on any of the claims if the single-source composition met the other limitations of that claim, such as fatty acid ratios. Pet.App. 29a-31a.

The Federal Circuit affirmed the Board's decisions on unpatentability under § 101 but did not directly address the product-by-process issue or

claim construction generally, and did not state explicitly whether it adopted the Board's construction or provide related reasoning. Pet.App. 10a-14a. Petitioner therefore concludes the court below adopted the Board's construction and supporting reasoning.

It was error to construe the claims as product-by-process claims. The claims are properly construed as standard composition claims and not as product-by-process claims. Strikingly, the decisions below provided no reasoning to support a product-by-process construction. They did not point to a recitation of process steps in any of the claims, or even to a verb suggesting a process step is required. *Cf. Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1371 (Fed. Cir. 2007) (stating that the claims under consideration "do not contain an explicit process-based limitation"). Notably, the term "intermixed" can be construed as a structural limitation rather than a process limitation. *See In re Garnero*, 412 F.2d 276, 279 (C.C.P.A. 1969) (listing "intermixed" as one of a number of similar terms, such as "etched and "welded," that have been "held capable of construction as structural, rather than process, limitations").

The Board also did not point to any disclosure or requirement in the specification or prosecution history for a specific process for preparing mixtures of lipids or fatty acids. *Cf. Andersen Corp.*, 474 F.3d at 1371 (where the claim does not recite a process-based limitation, the court "look[s] to the specification and the prosecution history" "to determine whether the claim language should be construed as containing any such limitation").

To the contrary, the specification supports construing "intermixture" as a structural limitation and not as a product-by-process limitation. For example, the specification states "[s]ome compositions may include two or more of: almond oil (2%-36%), anhydrous butter oil (2%-36%), coconut oil (0%-8%), corn oil (1%-24%), flaxseed oil (0%-8%), mustard oil (0%-8%), olive oil (2%-36), palm oil (0%-2%), peanut oil (4%-72%), pumpkin seeds oil (1%-24%), safflower oil (high oleic) (2%-60%), soybean lecithin (0%-4%), sunflower oil (high oleic) (4%-72%), and/or walnut oil (2%-36%)." Fed. Cir. App. Appx0081. The resulting formulation's composition necessarily differs from natural products. In fact, Petitioner provided evidence in the form of expert declarations teaching that "when lipids from different sources are intermixed, the resulting mixture will *necessarily* have different physical and chemical properties from a 'single' source." Pet.App. 30a; *see also* Fed. Cir. App. Appx7230-Appx7236, Appx7239-Appx7240. This follows from the fact that different sources have different compositions. *See*, *e.g.*, Fed. Cir. App. Appx0063-Appx0064 (listing oils and their nutrient components); *see also* Fed. Cir. App. Appx5703, Appx5472-5474, Appx6614-6622, Appx6650-6685.

2. The inconsistency between *Funk Bros.* and *Myriad* caused the court below to apply the wrong standard under 35 U.S.C. § 101

Owing to the tension between the *Funk Bros.* decision's constricted patent-eligibility standard and the *Myriad* decision's broader patent-eligibility standard that more closely comports with the founders' vision, the Federal Circuit, which adopted

each point of the Board's reasoning either explicitly or implicitly, did not apply a correctly articulated standard under § 101. *Funk Bros.* requires both that the claimed subject matter not be found in nature and, beyond that, more than a "simple step." *Myriad* requires no more than that the claimed subject matter be "new" and not found in nature. It reserves additional requirements for evaluation under other provisions of the patent statute. *See Myriad*, 569 U.S. at 595 n.9. ("We express no opinion whether cDNA satisfies the other statutory requirements of patentability."). Surprisingly, the Federal Circuit did not cite *Myriad* in its opinion. The Court should grant the present petition in order to clarify the proper standard.

The Federal Circuit adopted explicitly or implicitly the reasoning "that the claims are directed to natural products of walnut oil and olive oil, and that the additional limitations in the claims do not change the characteristics of the products, or add 'significantly more' to the claims." Pet.App. 11a.

This was error. All of the pending claims require a "dosage" of "omega-6 and omega-3 fatty acids" or a "dosage" of "omega-6 fatty acids." Pet.App. 68a-90a. All of the claims require a "formulation" that is "contained" in at least one "casing providing controlled delivery of the formulation to a subject." *Id.* All of the claims require that the recited casing comprise an "intermixture of lipids from different sources" or "intermixture of fatty acids from different sources." *Id.* Even if the claims required only one of these non-naturally occurring elements, such as a casing or a dosage, the resulting subject matter would fall outside the scope of natural products

under *Myriad*. That the claims require all of a dosage, a formulation contained in a casing, controlled delivery of the formulation to a subject, and an intermixture from different sources only reinforces the conclusion.

To the extent *Funk Bros.* requires a demonstration that the claimed subject matter adds 'significantly more' to the claims, the Court should hold that *Myriad* has implicitly overruled this requirement. *Myriad* indicates that, as long as the claimed subject matter is new and does not occur in nature, it is patent-eligible. This reasoning forms the foundation for the *Myriad* Court's finding that the BRCA1 and BRCA2 cDNA is patent-eligible while the corresponding genomic DNA is not. The Court did not reason that the cDNA adds 'significantly more' than that which is present in the corresponding genomic DNA. In fact, the Court acknowledged the cDNA does *not* add significantly more. Rather, it contains the same genetic information as the genomic DNA. The claimed genomic and cDNA differed only in that cDNA does not occur in nature. Similarly here, formulations in casings, for example, do not occur in nature. The Court held in *Myriad* that § 101 does not require more. *See Myriad*, 569 U.S. at 594-95.

The Federal Circuit agreed with the Board "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." Pet.App. 14a. This reasoning ignores the "dosage" and "casing providing controlled delivery of the formulation to a subject" limitations, as well as

the "intermixture" limitation. A formulation contained in a casing simply does not occur in nature. Thus, it has properties not possessed by natural products. Under *Myriad*, the degree of difference between what the court considers natural products and the claimed formulations is not at issue in determining whether subject matter is a natural product, *contrary to the reasoning in Funk Bros.*

The court affirmed the Board's conclusion "that the claims are directed to the omega-6 and omega-3 fatty acids that occur in nature, and that the asserted claim limitations do not distinguish the claimed products and compositions from those shown in the cited references." Pet.App. 14a. This is error for the same reasons as set forth immediately above. In short, "casing providing controlled delivery of the formulation to a subject," "dosage," and "intermixture" of fatty acids or lipids distinguish the claimed subject matter from omega-6 and omega-3 fatty acids by themselves.

The court explicitly or implicitly rejected petitioner's argument "that the claimed 'intermixture of lipids from different sources' does not occur in nature." Pet.App. 11a. For reasons set forth above, the court erred in rejecting this argument. The court's analysis relies on construing the claims as product-by-process claims, contrary to their plain language and the guidance provided in the specification. It is error to ignore claim limitations when construing claims. *See Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 29 (1997) (stating that "[e]ach element contained in a patent claim is deemed material to

defining the scope of the patented invention").[7] Further, Petitioner provided evidence in the form of an expert declaration teaching that "when lipids from different sources are intermixed, the resulting mixture will *necessarily* have different physical and chemical properties from a 'single' source." Pet.App. 30a; *see also* Fed. Cir. App. Appx7230- Appx7236, Appx7239- Appx7240. Thus, an "intermixture . . . from different sources" differs from what is found in nature.[8]

Consequently, such a mixture differs from "a new mineral discovered in the earth" (*Chakrabarty*, 447 U.S. at 309) at least because the claimed intermixtures are not identical to any single natural product, for the reasons stated. Even assuming, without conceding, that sunflower oil and coconut oil are natural products, a mixture of the two simply "is not naturally occurring." *See Myriad*, 569 U.S. at 595.[9] Like the cDNA in *Myriad*, it is "unquestionably" "something new."

Importantly, even if "intermixture" is properly

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[7] The rule applies generally, though stated in *Warner-Jenkinson Co.* with respect to claim scope under the doctrine of equivalents.

[8] For example, sunflower oil can have 2.652 grams of oleic acid per tablespoon and coconut oil can have 0.789 grams of oleic acid per tablespoon. *See* Fed. Cir. App. Appx0063 (Table 2). A mixture of 1 tablespoon each will have an intermediate concentration of oleic acid (about 1.7 grams per tablespoon).

[9] Petitioner maintains that oils derived from, for example, olive oil and walnut oil, are not natural products because the extraction processes used to make such oils cause chemical and physical changes in the oil constituents, resulting in a composition that is not found in nature. *See* Fed. Cir. App. Appx6614-6622, Appx6650-6685.

construed as a product-by-process limitation, this construction affects only the scope of the formulation itself. It does not affect the limitation that the formulation is contained in a casing providing controlled delivery of the formulation to a subject or that the formulation comprises a dosage of the recited fatty acids. Yet the court below ignored these limitations, contrary to binding precedent.

Specifically, in addressing anticipation, the court stated that "[t]he Board found that the 'casing' and 'dosage' terms do not impart patentability to the claimed compositions, and we agree, for the specification states that these claim elements are not limiting, and does not describe any assertedly novel characteristics of these components or their formulations." Pet.App. 6a.

The court's reasoning that "these claim elements are not limiting" in evaluating anticipation was error, and it was error to apply this reasoning in its § 101 analysis. This reasoning misrepresents or fails to appreciate that the specification does not state that these claim elements are not limiting, and because it impermissibly reads limitations out of the claims. *Warner-Jenkinson Co.,* 520 U.S. at 29.

As the court noted in support of its finding, the specification states "'the compositions comprising the lipid formulation disclosed herein may be administered to an individual by any orally accepted form.'" Pet.App. 6a (referring to the passage that corresponds to Fed. Cir. App. Appx0065). First, the quoted language is preceded by "[i]n some embodiments," so it does not apply to all embodiments, such as the embodiments recited in

the claims. In any event, this cannot reasonably be understood to mean that the claim limitation "casings," or containers, does not limit the claimed subject matter to formulations that are contained in a container. Moreover, the application discusses specific kinds of containers that can be used to deliver the formulations; these would be within the scope of the "casings" limitation. Fed. Cir. App. Appx0066 (referring to "a gelatinous case, a vial, a pouch or a foil"). Petitioner presented these arguments to the Federal Circuit. *See* App. Br. 29-30. Furthermore, petitioner's patent application specification expressly states that "[i]t is intended that the following claims define the scope of the disclosure and that methods and structures within the scope of these claims and their equivalents be covered thereby." Fed. Cir. App. at Appx97. All of this points to "casings" limiting the claims, contrary to the findings below.

Further, the person of ordinary skill in the art would have understood the term "dosage" to refer to "specified amount to ingest at one time or regularly during a period of time," which definition was submitted to the PTO during prosecution and was affirmed by the testimony of skilled persons, as petitioner argued to the Federal Circuit. *See* App. Br. 41-42, 44.

The court acknowledged petitioner's argument "that the claimed limitations of 'dosage' and 'casings providing controlled delivery' do not exist as natural products. The Applicant states that natural products cannot provide a controlled delivery or dosage because lipid profiles in nature are unpredictable," but implicitly rejected this reasoning. Pet.App. 11a.

For the reasons stated above, it was error to ignore these claim limitations in evaluating the claims under § 101.

3. No preemption

The scope of patentability must be limited to avoid the "considerable danger that the grant of patents would 'tie up' the use of" "basic tools of scientific and technological work" and thereby 'inhibit future innovation premised upon them.'" *Myriad*, 569 U.S. at 589. The formulations of the present claims do not pose a danger of such tying up.

In *Myriad*, the Court recognized that patent claims that encompass genes for breast cancer could preclude basic medical and scientific research that could yield, for example, more effective treatments for breast cancer. Thus, such claims could thwart rather than promote the progress of science. Unlike the *Myriad* claims that were directed to genomic DNA, which is not materially changed from the corresponding DNA as it is found inside the cell, the claims at issue here encompass only non-naturally occurring *combinations* of materials that are contained in a non-naturally occurring casing and that constitute a non-naturally occurring dosage of certain fatty acids. These claims do not preclude basic research on, or use of, any of the individual components of the claimed formulations. For example, even if walnut oil were properly considered a natural product and a component of the clai formulations, the claims do not encompass walnut oil itself. Were these claims to issue, they would not preclude anyone from making, using, selling, offering for sale, or importing walnut oil. Thus, the

reasons to exclude basic tools from patent eligibility do not apply to the present claims.

4. The present claims are not distinguishable on § 101 grounds from other issued patents that claim lipid formulations

The USPTO considers compositions that contain naturally occurring lipids to be patent-eligible. Petitioner has identified several such patents in non-exhaustive searches. U.S. Patent No. 5,198,250 (issued March 30, 1993) claims compositions that comprise "at least one lipid species containing at least one short chain monounsaturated fatty acid selected from the group consisting of C16:1n-7, C16:1n-6, C16:1n-5 C16:1n-7, C16:1n-6, C16:1n-5, C16:1n-4, C16:1n-3, C14:1n-5, C14:1n-4, C14:1n-3, and C12:1n-3 . . . present in said composition in amounts sufficient to improve" metabolic processing of lipids in an animal. *See* '250 patent 26: 20-30 (claim 1). The recited fatty acids "occur naturally." *See*, *e.g.*, *id.* at 9: 18-21. For example, C16:1n-7 occurs in olive and cottonseed oils, *inter alia*, and C14:1n-5 occurs in animal fat. *See id.* at 9: 24-34.

U.S. Patent No. 6,183,796 (issued Feb. 6, 2001) claims compositions produced, for example, by heating "isolated lower limbs of cattle to liquify the fat contained therein to produce an oil" and "[r]ecovering the oil to provide a natural lipid composition enriched in C14:1 monounsaturated fatty acid." *See* '796 patent at 5: 30-35 (claim 1, reciting the process) and at 6: 33-34 (claim 13, directed to "[l]ipid compositions produced by the method of any of" the preceding claims).

U.S. Patent No. 7,759,507 (issued July 20, 2010)

claims a "lipid system comprising naturally occurring oils" wherein the recited oils are present in certain ratios. *See* '507 patent at 24: 36-42 (claim 1). The claim contains no additional limitations. *See id.*

These issued patents establish, contrary to the decisions below, that compositions that contain certain naturally occurring lipids, without further limitation other than amounts or ratios, qualify as patent eligible subject matter. It follows, *a fortiori*, that the claims at issue here, which likewise require certain lipids or fatty acids derived from different sources and present in certain amounts and ratios, and further require a casing and a dosage of one or more fatty acids, also qualify as patent eligible.

5. Additional guidance in applying § 101 will benefit inventors, investors, USPTO, and the lower courts.

Increased certainty in the patent-eligibility standard will permit the courts and patent office to accurately apply the standard and not bar patent-eligible claims from issuing or from being enforced. It will also encourage and promote efficient investment of time, effort, and resources in innovation because the relevant parties will have greater understanding of what to expect. Patent protection will also nurture innovation by small entities as they try to compete with better-funded entities. These outcomes ultimately will benefit the public because resources will be employed more efficiently.

C. The Federal Circuit's decision should be vacated and remanded for failure to meaningfully review the Board's decision.

1. "Meaningful review" required

When a court reviews an agency's decision, "the Court has stressed the importance of not simply rubber-stamping agency fact-finding." *Dickinson v. Zurko*, 527 U.S. 150, 162 (1999) (citing *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 490 (1951)). "The APA requires meaningful review." *Id.*

2. No meaningful review of claim construction

The Federal Circuit affirmed the Board's decision in all respects. Pet.App. 2a. Claim construction played a key role in the Board's analysis. As discussed above, the Board addressed whether the claims are properly construed as product-by-process claims. Pet.App. 29a-31a. The Board's decision that the claims are product-by-process claims permitted it to ignore the claims' requirement for "an intermixture of lipids from different sources." It thus found the claims invalid under § 101 for reading on a single lipid source, walnut oil, which it characterized as a "product of nature." Pet.App. 31a-37a. It also relied on the product-by-process construction to find the claims invalid as anticipated by "Olives and 'Olives Nutrient Analysis'" (Pet.App. 50a-57a) and, independently, by "Walnuts and 'Walnut Nutrient Analysis (Pet.App. 57a-62a).

Petitioner contested the product-by-process construction on appeal. App. Br. at, e.g., 15-16, 18, 64. Yet the Federal Circuit did not address claim construction generally or the product-by-process construction specifically in its review of the Board's decision. The court's opinion does not refer to claim construction or claim interpretation except in a single reference to indicate that the "broadest

reasonable interpretation" standard applies. Pet.App. at 3a. Although the court recognized that "the Board's legal determinations receive de novo review," Pet.App. at 3a, it did not apply de novo or any other review to these issues.

The absence of a meaningful analysis or discussion of this contested and significant issue evidences the court's failure to meaningfully review an issue that petitioner contested and the Board decided. Consequently, the Court should vacate the Federal Circuit's decision and remand to require a determination of the proper construction of the claims at issue.

The outcome of this case would be reversed at least for independent claim 91 and its dependent claims if, on remand, it were determined that the claims are not properly construed as product-by-process claims, as argued above. Only a single reference, the "serving of walnuts as reported in the Walnut Nutrient Analysis," was found to anticipate claim 91, and, by extension, its dependent claims. *See* Pet.App. 3a, 7a, 8a; *see also* Exr. Ans. to App. Br. 47, 65, 73. This reference would not anticipate if the claim term "intermixture . . . from different sources" were construed to require more than one source of lipids, because walnuts constitute only one source of lipids. Further, if one or both of the claim elements "casings" and "dosage" were recognized not to be products of nature (discussed above), then claim 91 would be patent-eligible under § 101, as discussed above.

3. The Federal Circuit did not meaningfully review the Board's analysis of anticipation by the Mark reference

The Federal Circuit affirmed the Board's rejection of "claims 52, 61, 64, 65, 67-69, 73, 75, 77, 78, 80, 83, 90, 92-96, 98, 100, 129-131, 133, 135-137, 142 and 144 on the ground of anticipation by U.S. Patent No. 5,549,905 ["Mark"]." Pet.App. 3a, 10a, 14a. The court conclusorily set aside the "casing" and "dosage" limitations and failed to construe the claims with the required rigor. *See* Pet.App. 5a-6a (devoting a single paragraph to the issue). While the court affirmed a finding of anticipation of thirty claims, it specifically addressed only seven of these. The basis for finding the other twenty-three claims anticipated is not clear from the court's opinion. *See id.* 3a-6a.

4. Failure to meaningfully review anticipation of independent claim 91

The Federal Circuit did not meaningfully review the Board's analysis of anticipation of independent claim 91 and its dependent claims.

In its discussion of anticipation, the court did not address each of the four independent claims separately. The court stated that "claim 65 is the broadest claim" and "[o]ther claims add specificity of amounts or ratios, additional ingredients, sources of the lipids, and delivery methods." Pet.App. 2a-3a. Independent claim 91, at least, may be viewed as broader than claim 65, since claim 65 limits the ratio of omega-6 fatty acids to omega-3 fatty acids and claim 91 does not. Pet.App. 69a, 74a. Rather, claim 91 limits omega-6 fatty acids but not with respect to

omega-3 fatty acids, and it does not limit omega-3 fatty acids as a class. Pet.App. 74a.

Because each of claim 91 and claim 65 recite a material limitation that the other does not, any anticipation analysis of claim 65 does not apply to claim 91. Claim 91 stands rejected over only one of the cited references, "a serving of walnuts as reported in the Walnut Nutrient Analysis." Pet.App. 3a, 7a, 8a. The court's analysis referred to the omega-6/omega-3 ratio and the omega-6 less than 40 grams limitations, both of which occur in claim 65 but *neither* of which occur in claim 91. Pet.App. 8a, 69a, 74a. The court did *not* consider whether the reference disclosed the limitation "omega-6 fatty acids are greater than 20% by weight of the total lipids," which is present in independent claim 91 and its dependent claims. Pet.App. 8a-11a. The court therefore could not have fulfilled its obligation to meaningfully review the Board's finding of anticipation of claim 91 and its dependent claims.

That the Federal Circuit did not meaningfully review the rejections of claim 91 is further evidenced by the court's statement that "an omega-6 to omega-3 fatty acid ratio of 5:1" "is within the ratios in all of the '034 application claims." Pet.App. 4a. This statement suggests that the court did not appreciate that claim 91 is not limited with respect to "omega-6 to omega-3 fatty acid ratio." Pet.App. 74a.

5. Other instances of failure to meaningfully review

In the court's analysis under § 101, the court acknowledged petitioner's arguments that "the claimed limitations of 'dosage' and 'casings providing

controlled delivery' do not exist as natural products." Pet.App. 11a. Yet the court did not address or refer to these arguments in its § 101 analysis, and gave almost no analysis of these limitations in its anticipation analysis, as discussed above. *See* Pet.App. 11a-14a. A finding that these limitations establish that the claimed subject matter of *all* of the claims is not a product of nature would have defeated all of the § 101 rejections. This issue therefore should have received a reasoned analysis from the court. The Federal Circuit's glaring omission establishes that the court did not fulfill its obligation to meaningfully review the Board's findings of patent-ineligibility under § 101.

The court also failed to give meaningful review of numerous claims under §§ 101 and 102 because it provided few reasons to support its treatment of a large number of claims. *See* Pet.App. 3a-6a (treating anticipation of about thirty claims in three pages), 6a-10a (treating anticipation of over thirty claims over two references), 10a-14a (treating patent-ineligibility of about thirty claims).

A failure to provide meaningful review ultimately compromises judicial efficiency and fairness.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

/s/

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