No. 24-950

In the Supreme Court of the United States

URVASHI BHAGAT
Petitioner,

v.

THE UNITED STATES PATENT AND TRADEMARK OFFICE, COKE MORGAN STEWART[1], in her official capacity as Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office, UNITED STATES,

Respondents.

On Petition for a Writ to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

Urvashi Bhagat
Pro Se Petitioner
P.O. Box 1000
Palo Alto, CA 94302
(650) 785-2516
bhagatu@asha-nutrition.com

February 26, 2025

[1] Pursuant to Federal Rule of Civil Procedure 25(d), Coke Morgan Stewart, who is performing the functions and duties of the Under Secretary of Commerce for Intellectual Property and Director of the USPTO pursuant to 35 U.S.C. §3, is substituted for Katherine K. Vidal, her predecessor.

QUESTIONS PRESENTED

The Respondents and the U.S. patent courts are obstructing advancement in nutrition and prevention by unlawfully denying patents, neutering innovation in piecemeal patents, and arbitrarily forcing absurdly narrow patents causing the rising national burden of chronic and infectious (weakened immunity) diseases, violating the standard for advancement in the art mandated by the US Constitution Art. I §8 cl. 8, 35 U.S.C. §101, §103, *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966) and *Alice Corp. Pty. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355, 2358-2359 (2014). To reach obstruction, District Court repeatedly violated due process: refused to hear the Petitioner, unlawfully dismissed causes of action, refused timely request to enlarge discovery for good cause, refused to make explicit relevancy and reliability determinations of challenged Respondents' expert testimony, granted Respondents' premature Motion for Summary Judgment (MSJ) relying on challenged testimony despite pending appeal and Second Amended Complaint (SAC) seeking proper relief from issues raised in MSJ six weeks earlier, excising limitations from claims and disobeying *Graham* and *Alice* to deny patent under §101 and §103, then next day denied SAC entry. Federal Circuit affirmed the violations.

The questions are:

1. Whether lower courts erred in prejudice against innovation in nutrition arts in failing to uphold the constitutional standard of advancement ordained by Art. I §8 cl. 8, §101, §103, *Alice,* and *Graham* in failing to consider claims as a whole, failing to resolve level of skill in the art, failure of others, and unmet critical public health need?

2. Whether lower courts erred in holding new and useful processes, machine, manufacture, and composition of matter, reciting "formulations are so

packaged and labeled indicating suitability for consumption that collectively provide a [daily] dosage [based on cohorts] from 1 to 40g of omega-6 fatty acids and from 25mg to 10g of antioxidants, and wherein the antioxidants comprise one or more polyphenols [specific phytochemicals including polyphenols] in the dosage of greater than 5mg; wherein [the intermixture of] omega-6 fatty acid(s) and antioxidant(s) is not any single specific variety of a vegetable, a fruit, a nut, or a seed [almonds]," unpatentable under §101 over a variety of almonds disregarding the incontrovertible disclaimer, violating *Abbott Laboratories v. Sandoz, Inc.*, 566 F.3d 1282, 1288 (Fed.Cir.2009)), interjecting arbitrary interpretation into the claims contradicting the terms, and failing to construe specification as "legal instrument" defining the invention's scope "by the appended claims" violating *Markman v. Westview Instruments, Inc.,* 517 U.S. 370, 388 (1996)?

3. Whether the lower courts committed extreme due process violations, substantially disregarding and dismissing Petitioner's complaints, causes of action, motions and briefs, and imposing unfair procedure upon *pro se* Petitioner, violating *Snyder v. Com. of Mass*, 291 U.S. 97, 116, 137 (1934) mandate "the proceedings shall be fair." This includes:

a) Violating Fed. R. of Civ. Proc. (FRCP) 6(b)(1)(A) and 16(b)(4) and *Lujan v. National Wildlife Federation*, 497 U.S. 871 n.5 (1990), in denying Petitioner's informal request for extension of time before expiry of time, and providing lesser discovery time to Petitioner than Respondents?
b) Violating Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 (1993) and *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) in District Court's failure to make explicit relevancy and reliability determinations when Petitioner challenged Respondents' expert testimony as irrelevant and unreliable?

c) Violating FRCP 15(a)(2) and *Foman v. Davis*, 371 U.S. 178, 182 (1962) in District Court's grant of summary judgement in favor of Respondents while Petitioner's appeal and SAC conforming to new issues raised in MSJ filed six weeks before were pending and subsequent denial of SAC entry?

d) Violating 28 U.S.C. §1331 in denying jurisdiction granted to district courts for *all* civil actions arising under the Constitution, laws, or treaties of the United States, including actions against the United States, any agency thereof, or any officer without limitation on the amount in controversy (see Notes), and *Bowen v. Massachusetts*, 487 U.S. 879 n.48 (1988) in dismissing causes of action?

e) Violating Fifth Amendment of the Constitution and *United States v. Testan*, 424 U.S. 392, 401 (1976), *Jacobs v. United States*, 290 U.S. 13, 16 (1933), *First English Evangelical Lutheran Church v. Cnty. of Los Angeles*, 482 U.S. 304, 314-316 (1987), and *San Diego Gas & Elec. Co. v. City of San Diego*, 450 U.S. 621, 654 (1981) in denying self-executing waiver of sovereign immunity for damages from violations of due process of law and taking of property without just compensation?

f) Violating FRCP 8(a)(2) and (e), *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 556 (2007), and *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009), in requiring more than a short and plain statement of the claim construed to do justice?

g) Violating seventh Amendment right to jury trial in suits against the United States, ratified by *Law v. United States*, 266 U.S. 494, 496 (1925); *Hepner v. United States*, 213 U.S. 103, 115 (1909); *SEC v. Jarkesy,* 603 U.S. ____ (2024) (Slip Op. at 3, 22)?

h) Premature summary judgment and dismissal:

   i. Violating FRCP 56(b), 56(c), 56(d)(2) and *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) because close of discovery is appealed?

ii. Violating FRCP 56(c)(2) and *Tolan v. Cotton*, 134 S. Ct. 1861, 1866 (2014) because relevance and reliability of expert testimony is under appeal while relying upon the testimony?

iii. Violating *Markman* 517 U.S. 370, 387, and *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1370 (Fed.Cir.2018) in failing to hold claim construction hearing on §101 and §103 determinations when well-understood, routine, and conventional activities to a skilled artisan is a genuine issue of material fact?

iv. Violating FRCP 56, *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-26, 337 (1986), *Poller v. Columbia Broad. Sys., Inc.*, 368 U.S. 464, 473 (1962), and *Cantor v. Detroit Edison Co.*, 428 U.S. 579, 582 (1976), mandate for each court to consider entire record (that show that there is a genuine issue as to any material facts) applying all inferences in favor of the nonmoving party?

i) Violating *Altoona Publix Theatres v. American Tri-Ergon Corp.,* 294 U.S. 477, 487 (1935), and *Shelcore, Inc v. Durham Industries, Inc.,* 745 F.2d 621, 624 (Fed.Cir.1984), in using claim 82 as representative of 34 claims despite inventor's objections?

j) Violating *Weisgram v. Marley Co.,* 528 U.S. 440, 453–56 (2000), in failing to vacate judgment that impermissibly relied on challenged testimony?

This petition is an excellent vehicle to address significant bias against advancement in nutrition arts evidenced by multiple major violations cited above to obstruct important nutritional innovations, "so far depart[ing] from accepted ▯ course of judicial proceedings ▯ to call for an exercise of this Court's supervisory power" pursuant to Rule 10.

PARTIES TO THE PROCEEDING

All parties are listed in the caption.

CORPORATE DISCLOSURE STATEMENT

Asha Nutrition Sciences, Inc. owns 100% of U.S. Patent Application No. 13/877,847, 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 '847 application and is president of Asha Nutrition Sciences, Inc.

LIST OF PROCEEDINGS

United States Court of Appeals for the Federal Circuit
Appeal No. 2023-1545; *Bhagat v. The United States Patent and Trademark Office, et al.*
Judgment entered on April 3, 2024

United States District Court for the Eastern District of Virginia
Civil Action No. 1; 20-cv-1515; *Bhagat v. The United States Patent and Trademark Office, et al.*
Summary Judgment entered on March 30, 2023

The Supreme Court of the United States
Emergency Petition for Writ of Mandamus to District Court
Case no. 22-228; *In Re Urvashi Bhagat*
Petition Denied on October 31, 2022

TABLE OF CONTENTS

APPELLANT'S BRIEFS TO FEDERAL CIRCUIT

THE UNITED STATES CONSTITUTION, STATUTES and TREATIES

SUPPLEMENTAL APPENDIX:

TABLE OF AUTHORITIES

CASES

STATUTES

UNITED STATES CONSITUTION

UNITED STATES TREATY

RULES

OPINIONS BELOW

Federal Circuit opinion is published as *Bhagat v. United States,* No. 2023-1545 (Fed.Cir. Apr. 3, 2024). (App.5a-36a). Federal Circuit affirmed opinions and orders of the District Court (App.37a-66a). The order denying rehearing and rehearing *en banc* is unpublished. (App.67a-68a).

JURISDICTION

Federal Circuit entered its judgement on April 3, 2024. The Petition for Panel Rehearing or Rehearing En Banc was denied on August 21, 2024. Petitioner invoked this Court's jurisdiction pursuant to 28 U.S.C. §1254(1) and delivered the petition as per S.Ct.R. 29.2 within the time as extended by this Court on November 8, 2024, No. 24A469. On January 24, 2025, the Clerk mailed a notice to the Petitioner to file corrected form of the petition within 60 days. This corrected petition is timely filed in accordance with the notice.

UNITED STATES CONSTITUTION, STATUTES, and TREATIES

Pertinent provisions include, U.S. Constitution, Article I §8 cl.8, Amendments V and VII, 28 U.S.C. §1331, §1338(a), §1361, 35 U.S.C. §101, §103, and §145, and the Patent Cooperation Treaty (1970), reprinted at App.216a-220a.

STATEMENT OF THE CASE

The Petitioner has previously notified this Court[2] that USPTO and US Government in general are obstructing meaningful advancement in nutrition and prevention by unlawfully denying or forcing piecemeal patents (often as additives or narrow supplements) creating public health hazards. The piecemeal patents flood the markets with nutritional products that create excesses, deficiencies (excess of a nutrient can also create deficiency of another), or undesirable interactions and misinformation and disinformation as parties peddle their narrow products. (S.Appx348-349[3]). **Resulting extrajudicial patent policy fosters stagnation and is injurious to public health portending long-term public health crisis with rising epidemic of chronic and infectious (weakened immunity) diseases, warranting long overdue review from this Court.**

From 2008 to 2013, Petitioner filed three critically important interrelated patent applications 12/426,034 (USPA'034), 13/332,251 (USPA'251), and 13/877,847 (USPA'847), directed to defined dosages and tailored delivery of lipids (fat-soluble molecules), antioxidants, and other nutrients, most importantly omega-6 fatty acids which are critical for health yet so poorly understood in the prior art (discussed infra), to prevent excesses, deficiencies, and undesirable interactions among nutrients. (App.90a-93a; S.Appx353-354).

The disclosed innovations would mitigate chronic diseases and strengthen immunity averting infectious

---

[2] Case no. 18-277, Petition for Certiorari filed August 29, 2018; case no. 18-1274, Petition for Mandamus filed March 30, 2019; case no. 22-228, Petition for Mandamus filed August 17, 2022.

[3] S.Appx___ refers to Supplemental Appendix.

diseases, as the patent applications explain proper lipid intake is critical for health because they form structure of every cell are involved in critical cellular processes including gene regulation. Their derivatives are important hormones and biological messengers, affecting broad range of physiological functions such as vasal dilation, platelets aggregation, pain modulation, inflammation, immunity, and cell growth. The critical lipid requirements and metabolism are altered by hormones (gender and age) and antioxidants intake. Restricted and tailored intake of these substances is critical for health. (S.Appx.369-378).

Holding scope of the inventions against Petitioner, USPTO subjected each of the applications to extreme abuse in examination, forcing rejections by mutilating 35 U.S.C. §§100-103, the claims, and procedure; reconstructing prior art, refusing to answer arguments and evidence of poorly understood factors, and public suffering; delaying and neutering the innovations, and inducing other jurisdictions into imitation (documented in examination histories). Although 36 corresponding patents have issued[4] but after great delay and expense, damaging the Petitioner, her business, the innovations, and public health. (App.90a-96a).

USPA'034 was appealed to Federal Circuit in 2016 who regurgitated USPTO's imprudence, refusing to answer entirety of Petitioner's briefs and 100s of evidence documents, and forced §101 rejection on composition and process claims, even where USPTO admitted that composition does not exist in nature. (App.93a-94a). This Court denied certiorari (18-274)

---

[4] https://asha-nutrition.com/research/intellectual-property/

and mandamus (18-1274)[5]. USPA'251 was granted but after 10 years' drag and compromising the patent claims and implementation of the innovations. The present petition pertains to USPA'847, which has suffered similarly.

A. USPA'847

USPA'847 (S.Appx.347-416) is a Patent Cooperation Treaty (App.219a-220a) application that entered examination at USPTO under 35 U.S.C. §371 on April 4, 2013. There are 35 progressively narrower claims at issue: 8 independent, 18 product, 16 method, and 1 machine claim(s). (App.153a-169a). The broadest claims are as follows:

> 82. A packaged product comprising one or more nutritional formulations for an individual including at least one formulation comprising an intermixture of omega-6 fatty acid(s) and antioxidant(s) from different sources; wherein the one or more formulations are so packaged and labeled indicating suitability for consumption that collectively provide a dosage from 1 to 40g of omega-6 fatty acids and from 25mg to 10g of antioxidants, and wherein the antioxidants comprise one or more polyphenols in the dosage of greater than 5mg; **wherein the intermixture of omega-6 fatty acid(s) and antioxidant(s) is not any single specific variety of a vegetable, a fruit, a nut, or a seed.**

---

[5] Public objected to the denials given importance of the innovations and the chaos in patent eligibility. "Funk Brothers, Myriad & Products of Nature: How a Lack of Understanding Scientific Principles Is Damaging the Patent System." 49 Sw.L.Rev.330 (2020-2021); https://heinonline.org/HOL/LandingPage?handle=hein.journals/swulr49&div=17&id=&page=

> 99. A method for preparing a product comprising one or more nutritional formulations for an individual, the method comprising the steps of:
>
> (a) determining for the individual a diet cohort based on diet and/or a demographic factor of the individual; and
>
> (b) on the basis of the diet cohort, selecting and preparing one or more nutritional formulations for the individual, including at least one formulation comprising omega-6 fatty acid(s) and antioxidant(s);
>
> wherein the one or more formulations collectively provide to the individual a daily dosage from 1 to 40g of omega-6 fatty acids, and from 25mg to 10g of antioxidants comprising one or more polyphenols in a daily dosage of greater than 5mg;
>
> **wherein the omega-6 fatty acid(s) and antioxidant(s) are not any single specific variety of a vegetable, a fruit, a nut, or a seed.**

The claimed features in USPA'847 remain poorly understood in the art even today, over 100 years after identifying the problem. To date there is no teaching available on proportional dosages of total omega-6 fatty acids and antioxidants including polyphenols for optimal health in literature, including in the Dietary Guidelines for Americans, U.S.DHHS, or the most authoritative medical school textbooks. Moreover, these substances are randomly sold across the US touting high antioxidant intake. (App.142a-149a). Publications and product labels direct public to consult physicians on intake of fatty acids and antioxidants, but medical textbooks fail to teach medical students and physicians on requirements for these substances, even though they teach them to prescribe medications to "treat" various ailments

rooted in deficiency, imbalanced, or excessive intake of these substances. No teaching on substrate ingestion is provided to physicians or public, but medicines to modulate the substrate effects in-vivo are thrown at patients, which at best just ameliorate symptoms or at worst compound the problem. (App.91-92a; J.A.Appx7436-7438 [6]; J.A.Appx10924-10940). That is junk since!

Public cannot self-formulate lipids because they are highly unpredictable in nature (as much as 100%), even within species (e.g., same oil) based on cultivation conditions, and less than 1% of public can even correctly name basic types of fats. (J.A.Appx307-308; J.A.Appx10925-10927; J.A.Appx10981-10982).

B. Bad Faith Examination

Summation of conspiracy and bad faith deprivation of patent rights from USPA'847 is provided in the Complaints filed at the District Court (J.A.Appx298-318; J.A.Appx10984-11016), including:

- Refusing to honor Patent Prosecution Highway Agreements;
- Applying restrictions in violation of Patent Cooperation Treaty;
- Refusing to recognize multiple limitations in multiple claims;
- Refusing amendment to include disclaimer of natural products to force §101 rejections;
- Senior USPTO officers instructing the examiner to arbitrarily narrow the scope of the claims necessitating mixing all ingredients in one container that could harm public health from interactions;

---

[6] "J.A.Appx____" refers to Joint Appendix submitted to Federal Circuit.

- Refusing to enter expert testimony on record so it would not be available for appeal review;
- Rejecting claims for claim numbering order (which should be corrected post allowance);
- Reconstructing prior art in hindsight to force §103 rejections; and
- Refusing to recognize overwhelming evidence of poorly understood factors, poor expectation of success from prior art, and critical unmet public health need, submitted in *every response since July 2016*.

C. In 2018 USPTO Withdrew §101 Rejection but Forced Arbitrarily Narrow Claims 115-116, Despite Public Health Hazard, to Address Arbitrary §103 Rejections

Five years after filing of USPA'847, following numerous petitions for higher review due to bad faith examination, USPTO finally conceded the terms "mixture"/"intermixture" and disclaimer to single source overcome §101 rejection. However, USPTO imposed arbitrarily narrow claims 115-116 as "allowable" to address forced §103 rejection. (J.A.Appx3610; App.69a-71a).

"Allowable" Claim 115:

A nutritional composition comprising a mixture of:

a) 1-40 grams of omega-6-fatty acids selected from the group consisting of linoleic (C 18:2), conjugated-linoleic (C18:2), gamma-linolenic (C18:3), eicosadienoic (C20:2), di-homo-gammalinolenic (C20:3), and arachidonic (C20:4);

b) 25 mg-10g of an antioxidant selected from the group consisting of flavonoids, flavones, isoflavones, catechins, anthocyanidins, isothiocyanates, carotenoids, allyl sulfides,

terpenes, limonoids, phytosterols, beta carotene, ascorbic acid (vitamin C), folic acid, Se, superoxide dismutase (SOD), catalase, glutathione peroxidase (GSHpx), coenzyme Q10 (CoQ 10), glutathione and vitamin E;

c) and at least 5 mg of and of a phytochemical selected from the group consisting of monophenols, phytosterols, carotenoids, monoterpenes, saponins, lipids, triterpenoids, betalains, organosulfides, indoles, glucosinolates, and sulphur compounds;

wherein the omega-6-fatty acids, antioxidants and phytochemicals is not any single specific variety of vegetable, fruit, nut or seed.

USPTO's "allowable" claims would force the Petitioner to always mix components in one container. Petitioner explained mandatory mixing in one container is a public health hazard, because these components can interact forming harmful compounds. Without deleting alternate claims, Petitioner accepted slightly modified version of claims 115-116 to allow multi-dose packaging (as in cough syrups) (App.166a-167a). Claims 82 and 99 recite "one or more nutritional formulations" to allow multi-container formulations to minimize harmful interactions ("one" formulation has been claimed for special formulations, like feeding tubes). **USPTO did not care about public health hazard** and rejected all claims 82-120, including claims 115-116 substantially drafted by USPTO. (J.A.Appx310; J.A.Appx10993-10994).

D. PTAB Maintained Arbitrary Rejections

USPTO's bad faith actions and misconduct continued even in appeal review, such that 99% of arguments and 100% of the evidence within cited art

and peer-reviewed scientific papers evidencing overwhelming opposite teachings and critical unmet public health need (J.A.Appx4744-4750; J.A.Appx4767-4845) were disregarded. Patent Trial and Appeal Board (PTAB) panel issued a final decision on October 7, 2020, denying the patent under the pretext of indefiniteness, improper dependency, and obviousness under §112 and §103. (J.A.Appx6477-6488). Thus, patent was improperly denied eight years after filing date.

Petitioner did her utmost to avoid the expensive civil action begging the Chief Judge of PTAB to fairly decide the matter in five petitions, but to no avail. (J.A.Appx11016-11017). Section 145 action had to be filed at District Court because the Respondents had refused to enter Petitioner's expert testimony on record to damage appeal review (J.A.Appx310; J.A.Appx10998). During the ***15 years*** of abuse since the Petitioner's first application was filed in 2008, the Respondents have caused enormous damage to Petitioner's life and business, making the demand for damages and just compensation for Taking necessary. (J.A.Appx299-300; J.A.Appx11012-11015).

D. District Court Proceedings

Complaint:

The civil action was timely initiated at the District Court on December 9, 2020 (J.A.Appx35). First Amended Complaint (FAC) was timely filed on April 19, 2021 (J.A.Appx297-322), asserting USPTO is guilty of misconduct and bad faith invading Petitioner's constitutionally protected patent rights, that Petitioner has been entitled to patent grant for many years, claiming relief under the Fifth Amendment's Takings clause due to the extraordinary delay in patent grant, and claiming relief for damages

to Petitioner's company, livelihood, and life, because USPTO actions:

- created bias against the patent application and the business;
- stalled venture financing and licensing deals;
- caused loss of most opportune market timing;
- delayed and compromised several of Petitioner's critical patents because USPTO actions were imitated by other patent offices;
- multiplied legal burden because many responses, appeals, and legal actions had to be filed in US and many jurisdictions due to USPTO's bad faith actions; and
- caused enormous expense, mental anguish, and loss of livelihood to Petitioner.

(J.A.Appx298-300).

The Complaint timely asserted that District Court has jurisdiction and venue pursuant to 28 U.S.C. §1331, §1338(a), §1361, and §1391(b)(1)-(2), §1391(e), and 35 U.S.C. §145. The Complaint also demanded Seventh Amendment right to jury trial. (J.A.Appx304, 318).

Improper Dismissals:

On July 22, 2021, on Respondents' motion District Court dismissed Petitioner's interdependent causes to damages, Takings, declaratory/injunctive relief, and claims to invasion of constitutionally protected patent rights, and misconduct and false statements made by USPTO, refusing to acknowledge significant parts of FAC including invocation of jurisdiction under §1331, §1338(a), and §1361, and struck jury trial without answering Petitioner's brief in opposition. (App.37a-43a; App.102a-110a; App.187a-193a).

Petition for Mandamus to District Court from improper dismissals was filed at this Court on August 17, 2022, asserting Petitioner anticipates further

violations absent mandamus (case no. 22-228). This Court denied review on October 31, 2022, without implicating merits[7].

Higher Litigation Burden Imposed Upon Pro Se Petitioner and Denial of Adequate Discovery:

Because of higher litigation burden imposed on *pro se* Petitioner by District Court requiring paper filings shortening/eliminating her response time, and due to illness among her experts in late November, Petitioner was unable to meet close of discovery deadline of December 9, 2022. Citing good cause, Petitioner made multiple informal requests for discovery extension from November 20 to December 5, 2022, in accordance with FRCP 6(b)(1)(A) and 16(b)(4) and *Lujan* n.5. Due to lack of response, formal motion was made on December 14, 2022. (App.110a-118a; 193a-197a). The District Court not only denied the requests and motion but barred Petitioner from making informal requests violating FRCP 6(b)(1)(A), 16(b)(4) and *Lujan*. (App.44a-51a).

Petitioner filed Notice of Appeal (NOA) from improper close of discovery on January 13, 2023. (J.A.Appx8326).

Failure to Exclude Inadmissible Respondents' Expert Testimony:

On December 14, 2022, Petitioner filed a motion to disqualify Respondents' expert testimony as inadmissible for irrelevance and unreliability for failing Federal Rules of Evidence (FRE) 104, 402, 403, 405-406, 702, with 500-page evidence. (App.118a-126a; 197a-201a). District Court denied the motion in one sentence under the pretexts of bias not admissibility without any relevancy and reliability

---

[7] *Maryland v. Baltimore Radio Show, Inc.*, 338 U.S. 912, 918-919 (1950).

determinations violating FRE 702 and *Daubert* 592 and *Gen. Elec. Co.* 136, 146. (App.52a).

Petitioner amended NOA to include improper denial of expert disqualification on January 30, 2023.

Respondents' MSJ Resurrected Withdrawn §101 Rejection, Cited New Art, and Reconstructed Art to Allege §101 and §103:

On January 20, 2023, Respondents filed Motion for Summary Judgment (MSJ) resurrecting withdrawn §101 rejection over naturally occurring almonds, and §103 rejections citing new prior art. (App.128a-129a; App.202a). On January 31, 2023, Petitioner filed objections to premature MSJ requesting striking, denying, or stay of MSJ because close of discovery and denial of expert disqualification are appealed, claim construction hearing is not held, and record is rife with disputed facts citing FAC, expert testimonies, and prior art analyses. (App.130a-137a; App.203a-205a).

SAC Was Filed In-part to Seek Proper Relief from New Rejections and Citations in MSJ:

Petitioner filed Second Amended Complaint (SAC) on March 15, 2023 (J.A.Appx10908-11032), disputing new issues raised in MSJ filed six weeks earlier and for proper relief on merits on evidence crystallized during discovery. (App.126a-130a; App.201a-203a).

Improper Summary Judgement:

On March 30, 2023, District Court denied Petitioner's objections to MSJ and granted summary judgment in Respondents' favor (App.53a-65a) while interlocutory appeal on close of discovery and admissibility of expert testimony and SAC were pending, without holding claim construction hearing, on record rife with disputed facts, admitting to disputed facts, "Plaintiff asserts that Morris teaches

away" (App.63a), relying upon the challenged expert testimony and new rejections and citations (App.63a). (App.53a-64a; App130a-137a; App.203a-205a); while summary judgment fails as a matter of law on §101 and §103 because limitations from 35 claims were excised and poorly understood factors were disregarded. (App.137a-149a; App.205a-214a).

Denial of SAC Entry:

On March 31, 2023, day after improper judgement, District Court denied SAC entry without justifying reasons in violation of FRCP 15(a) and *Foman* 182. (App.66a).

Notice of Appeal Amendments:

Petitioner amended NOA several times to include improper grant of summary judgment, denial of SAC entry, and to include final judgment. (J.A.Appx14000-14001).

D. Federal Circuit Proceedings

Federal Circuit jurisdiction was invoked under 28 U.S.C. §1295(a)(1). Federal Circuit regurgitated Respondents positions and district court decisions, disregarding almost entirety of Petitioner's briefs and record on appeal, and numerous limitations from claim 82, and 34 claims in entirety despite Petitioners objections to representative claim approach (App.72a-215a; App.171a; App.184a-185a), and affirmed each of District Court orders on April 3, 2024, and denied rehearing and rehearing *en banc* on August 21, 2024. (App.5a-36a; App.67a-68a). Federal Circuit decision conflicts with numerous of this Court's, Fourth Circuit's, and its own precedents, cited *infra*, and even contradicts its decision in Petitioner's 2016 appeal advising disclaimer in claims. (App.179a-180a).

REASONS FOR GRANTING THE PETITION

I. Lower Courts are Failing the Overriding Standard of Advancement Ordained by US Constitution Art. I §8 cl.8, 35 U.S.C. §101, §103, *Diehr*, *Graham*, and *Alice* in Nutrition Arts—Resulting Extrajudicial Patent Policy is Irreparably Harming Public Health

(1) *Common Standard of Advancement in Art. I §8 cl.8, §101, §103, Diehr, Graham, and Alice Requires Assessment of Claims "as a Whole" in "Ordered Combination" In Light of Level of Skill in the Art, Failure of Others, and Unmet Need:*

Constitution Art.I §8 Cl.8:
"To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[8]

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."

Thus, in identifying patentable subject matter, both Const. Art.I §8 Cl.8 and §101 mandate consideration of "useful" arts or "new and useful improvement thereof," which necessitates consideration of claims as a whole.

This Court also mandated in *Alice, Mayo,* and *Diehr* that claims are considered "as a whole" "both

[8] All emphasis is added, unless otherwise stated.

individually and "as an ordered combination" in light of "well [or poorly] understood, routine, or [un]conventional activity," designed to solve a problem for §101 analysis. *Alice Corp. Pty. v. CLS Bank Int'l*, 134 S.Ct. 2347, 2355, 2358-2359 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289, 1298 (2012); *Diamond v. Diehr*, 450 U.S. 175, 188 (1981).

Advancement analysis is dispositive here, as no law of nature exception applies. (App.34a; App.58a). *Mayo* 1303.

Advancement analysis is also mandated by §103 and *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

35 U.S.C. §103:

"A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made."

Graham explained:

"In §103 of the 1952 Patent Act, Congress added the statutory nonobvious subject matter requirement [] requiring a comparison of the subject matter sought to be patented and the prior art, tying patentable inventions to advances in the art." *Id* 2.

Graham at 17 mandated following inquiries to assess advancement under §103:

i. scope and content of the prior art are to be determined;

ii. differences between the prior art and the claims at issue are to be ascertained;
iii. the level of ordinary skill in the pertinent art is resolved; and
iv. secondary considerations as long felt but unsolved needs and failure of others are utilized to give light to the circumstances.

Thus, each of Art.I §8 cl.8, §101, §103, *Alice, Mayo, Diehr*, and *Graham* tie patentable subject matter "as a whole" in "ordered combinations" to advances in the art, and poorly/well understood factors are relevant to both §101 and §103 analyses, which were violated by lower courts, demonstrated infra.

(2) *Lower Courts' Sweeping Construction of Natural Phenomena and Abstract Idea Disregarding Numerous Claim Limitations Violates §101, Diehr, Mayo, Alice, and Myriad, and Threatens to Swallow the Patent Law:*

As asserted *supra*, USPTO conceded that instant claims are not drawn to patent-ineligible concept and withdrew §101 rejection in 2018. (App.69a-71a). §101 rejection over almonds was improperly resurrected in Respondents' MSJ. Lower courts rubber-stamped the impropriety (App.34a, App.58a-59a) despite that each claim contains specific processes, manufacture, and composition limitations, and disclaims natural phenomena, like almonds, as follows:

> "A packaged product [**manufacture**] comprising one or more nutritional formulations [**composition**] for an individual [**process**]... comprising an intermixture of omega-6 fatty acid(s) and antioxidant(s) from different sources [**composition**]...so packaged and labeled indicating suitability for consumption that collectively provide [**process** and **manufacture**] a [daily] dosage [based on diet cohorts including medical conditions] from 1

> to 40g of omega-6 fatty acids and from 25mg to 10g of antioxidants, and wherein the antioxidants comprise one or more polyphenols [and specific phytochemicals] in the dosage of greater than 5mg [**process** and **composition**]; wherein the intermixture of omega-6 fatty acid(s) and antioxidant(s) is not any single specific variety of a vegetable, a fruit, a nut, or a seed [**disclaimer to natural phenomena, e.g., almonds**]." (App.153a-169a) ([...] denote narrower limitations from claim 82 in claims 99 and 115-116; [**boldface**] denotes §101 patent-eligibility).

Notably, selection of "dosage" "for an individual" a "specified amount of a substance for ingestion at one time or regularly" (J.A.Appx301, 305; J.A.Appx10924-10925), is a **process** under §100(b).

Whereas claims 88, 96-98, 116 include additional **processes** for administering/treating medical conditions (App.157a-158a; App.167a-168a).

This Court instructed in *Mayo* 1296-1297 and *Alice* 2355, first we determine whether the claims at issue are directed to a law of nature, natural phenomena, or abstract idea. Instant claims recite multiple process, manufacture, composition, and machine limitations. These are not only not directed to a patent-ineligible concept, but they also expressly disclaim natural phenomena, like almonds.

Federal Circuit dismissed the disclaimer alleging, "nutritional compositions Bhagat seeks to claim exist in nature." (App.34a).

Nothing could be farther from truth!

First, nature cannot provide claimed dosages with any reliability, argued umpteen times (FAC J.A.Appx307; expert testimonies J.A.Appx7457-7459,

J.A.Appx7585-7587), let alone provide daily dosages based on demographic factors in claim 99.

SAC (J.A.Appx10926-10927) asserts:.

> "Differences in almond oil fatty acid profile attending to almond origin have been widely described (Garcia-Lopez et al., 1996; Kodad and Socias I Company, 2008; Yada et al., 2011; Maestri et al., 2015). In order of importance, the main fatty acids that appear in almond oil are oleic (50–80%), linoleic (11–37%), palmitic (5–16%) and stearic (1–4%) acids (Askin et al., 2007). Linolenic acid appears in concentrations lower than 0.1% (Maestri et al., 2015) although percentages higher than 11% have been reported in some cultivars (Askin et al., 2007)." Rabadán et al., "Suitability of Spanish almond cultivars for the industrial production of almond oil and defatted flour" Scientia Horticulturae Volume 225, 18 November 2017, Pages 539-546..."

Irrespective of whether content of nutrients in a variety of almonds fall within the claimed dosages, the variability in nature is so extreme that it cannot be considered to provide "a dosage," "specified amount of a substance for ingestion at one time or regularly."

Second, lower courts failed to address the specified dosages, let alone totality of any claim in ordered combination failing to explain how many almonds is product of nature that provides the dosages "from 1 to 40g of omega-6 fatty acids and from 25mg to 10g of antioxidants", let alone "daily dosage" (App.34a; App.58a-59a), mandated by *Alice* 2355, *Mayo* 1298, and *Diehr* 188.

Third, this Court instructed in Myriad that dictated by nature is not the test finding cDNA to be patent eligible, even if the sequence occurs in nature. *Ass'n*

for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 595 (2013). Mutatis-mutandis present mixtures and integrated processes and manufacture are patent-eligible.

Fourth, indisputably the disclaimer to single source nuts/seeds can't be excised, based on Federal Circuit's own precedents and this Court's precedents. Applicants can incontrovertibly disclaim matter, *Abbott Laboratories v. Sandoz, Inc.*, 566 F.3d 1282, 1288 (Fed.Cir.2009)(en banc). USPA'847 is "a legal instrument, to be construed, like other legal instruments, according to its tenor," which is to balance nutrient delivery from different sources (S.Appx348-351), mandating "the scope of the present invention is defined by the appended claims" S.Appx354 ¶22). *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388 (1996); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed.Cir.1995)(*en banc*) (contradiction of claim terms is prohibited).

Federal Circuit also dismissed claim 112 in one sentence as "abstract idea of meal planning" (App.34a) disregarding ordered combination of complex eight-part specific configurations. (App.163a-165a).

Claim 112 is directed to special application of **machine** (computer) "to a new and useful end," integrating the computer with eight-part special configurations, to implement complex process of claim 99, to provide daily dosages of omega-6 fatty acids and antioxidants based on diet cohorts "in response to remote user inputs" (App.163a-165a), a problem that prior art has neither understood nor solved (discussed *supra* and *infra*) and is patentable, per *Diehr* 177-178.

Thus, instant claims encompass multiple specific process, manufacture, composition, and machine limitations "to a new and useful end" of delivering tailored dosages of omega-6 fatty acids and

antioxidants in the broadest embodiments with additional limitations in narrower embodiments. There is no preemption and no tying up of building blocks of human ingenuity! *Mayo* 1301.

Because claims are not directed to laws of nature, natural phenomena, and abstract ideas, §101 inquiry is over at step one *Mayo* 1296-97, *Alice* 2354-55, and *Myriad* 2116; the claims fall within the ambit of §101.

Federal Circuit disregarded these arguments. (App.137a-140a; App207a-209a).

Such sweeping construction of §101 threatens to swallow all of the patent law, "At some level, 'all inventions...embody, use, reflect, rest upon, or apply...natural phenomena, or abstract ideas." *Alice* 2354.

(3) *Lower Courts Violated Common Standard of Advancement Under §101 and §103 Failing to Consider Claims "as a Whole" in "Ordered Combination" Disregarding Overwhelming Evidence of Poorly Understood Factors, Failure of Others, and Unsolved Need:*

This Court admonished in *Diehr* 188-89 "In determining the eligibility of respondents' claimed process for patent protection under §101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made." Also see *Alice* 2355, 2358-2359, and *Mayo* 1298.

As established in Section I.(1) *supra*, "as a whole" analysis considering level of skill in the art, failure of

others, and unsolved need is also mandated by §103 and *Graham* 3, 15, 17 for obviousness analysis,.

Yet lower courts failed to provide reasoned analysis of any of the 35 claims at issue involving process steps in ordered combination of limitations violating §101, §103, *Diehr*, *Alice*, *Mayo*, and *Graham*.

First, lower courts failed to consider the ordered combination central to all claims: "dosage from 1 to 40g of omega-6 fatty acids and from 25mg to 10g of antioxidants, and wherein the antioxidants comprise one or more polyphenols in the dosage of greater than 5mg," in either §101 or §103 analysis (App.34a-36a; App.58a-63a), despite Petitioner's arguments asserting their import. (App.139a-140a; App.209a-210a).

Rather than analyzing claims "as a whole" in "ordered combination," the lower courts dissected the claims disregarded specific dosages and compositions as "combination of nutrients found naturally in almonds" and then ruled, "additional claim elements such as packaging, labeling, administering [new uses], preparing, and computer-automating are [] conventional activities" (App.34a; 60a-62a), while disregarding countless additional limitations in 34 claims (App.153a-169a).

Second, lower courts had no admissible evidentiary basis to resolve "well-understood, routine, or conventional activity" or "level of ordinary skill in the...art" required by *Alice*, *Mayo*, *Diehr*, and *Graham* because Respondents' expert testimony had been challenged as inadmissible and is under appeal, weighing of which at summary judgment in favor of movant is prohibited. FRCP 56(c)(2); *Tolan v. Cotton*, 134 S.Ct. 1861, 1866 (2014); and *Weisgram v. Marley Co.*, 528 U.S. 440, 453–56 (2000). (App.52a; App.63a;

App.119a-126a; App.132a-133a; App.141a-142a; App.197a-201a; App.204a; App.210a-211a).

Third, lower courts disregarded overwhelming evidence of poorly understood factors submitted by Petitioner within the cited art and the prior art as a whole under §101 and §103 analyses. See App.141a asserting, "the '847 application and Appellant's expert testimony demonstrate claims as a whole are not well-understood" citing "Section V.C. supra, Table 3 infra," and App.142a-148a includes Table 3 citing overwhelming evidence of poorly understood factors before the District Court in:

- USPA'847 (2010 priority)
- Scientific publications *Lands-NIH* (2005), *Niki* (2009), *Mennen* (2005), *University of California* (2008), *Harris* (2002-2019)
- Four Petitioner's Expert Testimonies (2022)
- Dietary Guidelines for Americans (2000-2025)
- Harrison's Principles of Internal Medicine (2018)
- Institute of Medicine, 2005 Dietary Reference Intake
- Cited Art *Morris* (2008), *Anthony* (2007), *Howard* (2003), *Debbouz* (2008), *Rusing* (2007)
- Randomly sold products comprising omega-6 fatty acids, antioxidants, and polyphenols (2022)

Petitioner also submitted tables delineating detailed differences between cited art and claims at issue demonstrating poorly understood factors (J.A.Appx8264-8292), exemplified by *Morris* (S.Appx8264-8271; S.Appx9401-9424) analysis below:

- Omega-6 is not essential and replaceable with omega-3 (¶¶46, 50, 53, 59, 62, 66, 69); no or zero omega-6 in formulations 1-6; and 0.070g in

formulations 7-27 (70mg GLA); versus 1g-40g omega-6 in present claims

- No suggestion on proportional dosage of total antioxidants including polyphenols
- Open-ended dosages of antioxidants add up to significantly more than 10g restriction in present claims, e.g., 31g/day (formulation #27 is about 15,000mg/day (three times daily ¶164) and claims 1+2+3+4+9+13+18+19 yields antioxidants over 24,000mg/day).

Also see App.211a-214a.

Each of the above evidence that there is no suggestion of proportional dosage of total omega-6 fatty acids and antioxidants including polyphenols in the prior art, i.e., no reason to combine elements as claimed because problem is not understood. *KSR Int'l Co. v. Teleflax*, 127 S.Ct. 1727, 1731 (2007). Moreover, prior art overwhelmingly taught and continues to teach extremely low omega-6, e.g., less than 1g/day, and excessive antioxidants including polyphenols, significantly above 10g/day, demonstrated above.

Fourth, lower courts misrepresent that there were no disputed facts or poorly understood factors arguments were belated (App.33a-36a; App.57a), as these were submitted repeatedly since 2010 in:

- USPA'847 2010-2011 filings (S.Appx349-355, S.Appx358-359, S.Appx369-373, S.Appx394-395),
- publications and responses filed at USPTO since 2013, included in administrative record before District Court (J.A.Appx3807-3834; J.A.Appx10987-10994),
- three complaints filed at the District Court 2020-2023 (J.A.Appx301-302; J.A.Appx305-307) (J.A.Appx10924-10983),

- expert testimonies and supporting evidence filed at District Court in 2022 (J.A.Appx7130-7163; J.A.Appx7189-7203; J.A.Appx7457-7546; J.A.Appx7585-7667; J.A.Appx7669-7714), and
- opposition to MSJ filed in 2023 (J.A.Appx9911-9912) citing expert testimonies and numerous publications on record, and
- the briefs and Joint Appendix filed at Federal Circuit (App.141a-149a; App.205a-207a).

District Court contradicted itself admitting to disputed facts, "Plaintiff asserts that Morris teaches away because its examples contain no or low amounts of omega-6 fatty acids..." and "does not address the problem solved" (App.63a) yet granted the summary judgement in movant's favor.

Fifth, each court is mandated to consider entire record when deciding/reviewing summary judgment by FRCP 56, *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-26, 337 (1986), *Poller v. Columbia Broad. Sys., Inc.*, 368 U.S. 464, 473 (1962), and *Cantor v. Detroit Edison Co.*, 428 U.S. 579, 582 (1976), (the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, that show that there is a genuine issue as to any material facts) and apply all inferences in favor of nonmovant, which was violated by lower courts (App.33a; App.57a), despite Petitioner's objections (App.143a; App.184a; App.206a-207a).

Sixth, lower courts misrepresent that Petitioner did not put forth arguments as to teaching away and unexpected results from prior art or that statements were conclusory. (App35a-36a; App.63a). Sufficient arguments were submitted for a mind willing to understand. (App.143a-148a; App.210a-214a). District Court admitted that "Plaintiff asserts that Morris teaches away because its examples contain no

or low amounts of omega-6 fatty acids..." (App.63a). Furthermore, teaching away and unexpected results have been argued extensively in FAC (J.A.Appx305-306), expert testimonies (J.A.Appx7139-7157; J.A.Appx7196-7202; J.A.Appx7481-7522; J.A.Appx7609-7655), and SAC (J.A.Appx10958-10975).

Seventh, lower courts failed to address secondary considerations as failure of others and long-felt but unsolved needs (App.33a-36a; App.57a-63a) mandated by §101, *Diehr* 177-178, §103, and *Graham* 17, despite Petitioner's arguments and expert testimonies (App.148a-149a; J.A.Appx7131-7132; J.A.Appx7153-7158; J.A.Appx7202; J.A.Appx7522-7536; J.A.Appx7648-7657), including esteemed scientist, Dr. Erickson's testimony:

> "Although it was known in the art that high dosages of polyphenols could be harmful to health Harris, Mennen, Morris, Dietary Guidelines for Americans, IOM, and University of California and others failed to solve the problem in teaching dosages of polyphenols proportional to omega-6 intake, including that polyphenols 'increase the requirement for omega-6'. Therefore, the others tried and failed to meet the need. This is evidence of non-obviousness... Abundant evidence has been provided in the '847 application that multiple chronic and infectious diseases can be prevented and mitigated by the claimed inexpensive solutions. It is irresponsible not to implement and nurture the claim[ed] solutions. It is irresponsible to direct the public [to] pharmaceutical treatments for numerous diseases when preventative, less expensive and less burdensome alternatives can be incorporated." (App.149a; J.A.Appx7657).

Federal Circuit demonstrated bias against nutritional arts in failing to uphold "[A]dvancement in the art is the overriding constitutional standard... 'to be implemented by the [] courts,'" and evidence of failure of others to provide a feasible solution to the long-standing problem is most probative, *In re Piasecki*, 745 F.2d 1468, 1472-1473, 1475 (Fed.Cir.1984), mandated by *Graham* 17.

Thus, lower courts failed to uphold standard of advancement mandated by §101, §103, and this Court's precedents *Diehr*, *Alice*, *Mayo*, *Graham*, and *KSR*.

(4) *Prejudice Against Advancement in Nutritional Arts is Unconscionable and Damaging to Public Health:*

As explained supra and throughout USPA'847 (S.Appx347-416), very significant advancement in nutrition and prevention and public health can be achieved by implementation of these innovations, and that public cannot self-formulate these substances because of extreme variability in nature and 99% of the public cannot even name lipids. Further, implementation of these innovations can pave the way for very significant reduction in national healthcare expenditures. (App.95a-96a).

Eighteen countries have issued corresponding patents with substantially same claims as at issue[9], demonstrating improper US decisions, despite common PCT standards. (App.219a-220a).

Respondents and lower courts have repeatedly refused to hear the Petitioner, demonstrating reflexive prejudice against advancement in nutrition arts.

---

[9] https://asha-nutrition.com/research/intellectual-property/

For example, Respondents' arbitrarily narrow "allowable" claim 115 recited supra restricted to 40g of omega-6 fatty acids and 10g of antioxidants—absolute amount not dosage—mixed in one container is **antithesis** of advancement at least because mandatory mixing is public health hazard (J.A.Appx310; J.A.Appx10993-10995). Such mindless narrow products flooding the markets foster stagnation and misinformation, rather than advancement in nutrition arts. USPTO has issued about 135,000 patents directed to various narrow fatty acids patents, i.e., roughly 2.7 million years of monopolies (@20 years/patent) instead of granting a proper 20-year patent as claimed to eradicate the problem. (J.A.Appx302; J.A.Appx10984).

Why such arbitrary limits on advancement in nutrition? Moreover, then the patent system is being used to advance harmful arts violating US Constitution Art. I §8 cl. 8, §101, *Diehr*, *Alice, Mayo*, §103, and *Graham*?

There does not appear to be any prejudice against patents to air or water purification technologies, despite broad applications. See issued patents US12161972, US3670897A, and US-4125463-A.

Similarly, present innovations are designed to take excesses and deficiencies out of natural phenomena by means of controlled delivery and use of complementing different sources—equivalent to removing impurities. These innovations will bring about much needed advancement in nutrition and should be nurtured with limited exclusivity.

These will spur downstream innovations in nutrition arts. As *Graham* Court proclaimed there is great power in limited monopoly to "incite 'ingenuity'", *Id.* 8, and urged, "evenhanded application" including in "less technical, but still useful, arts." *Id.* 19.

(5) *Risk of Permanent Loss of Advancement*

Without patent grants these innovations might be permanently lost to the detriment of public health, because after the Petitioner's disclosure the subject matter is anticipated and obvious and unpatentable to others, and without patent incentives, small margins and significant capital and extensive public education needs deter implementation. Education alone is insufficient due to unpredictability in nature and complexity of solutions. As *Graham* 11 guides, patents induce inventions that might not otherwise occur.

II. Egregious Due Process Violations by Lower Courts Resulting in Manifest Injustice

(1) *Federal Circuit Refused to Hear the Petitioner That District Court Provided 10% Less Discovery Time to Her and Denied Extension Violating FRCP 6(b)(1)(A) and 16(b)(4) and Lujan Unfairly Affecting the Outcome*

FRCP 6(b)(1)(A) expressly provides for extension of time, "with or without motion or notice...if a request is made, before the original time or its extension expires..."

FRCP 16(b)(4) provides, "a formal motion is not necessary" to modify the discovery schedule. Notes of Advisory Committee on Rules—1983 Amendment.

Lujan v. National Wildlife Federation, 497 U.S. 871 n.5 (1990) upholds FRCP 6(b)(1) for making "request...'with or without motion or notice,' provided the request is made before the time for filing expires." *Id.* n5.

Petitioner's FRCP 6(b)(1)(A), 16(b)(4), and *Lujan* discovery extension requests to District Court were properly made on November 20-22, 2022, and

December 1st, 5th 2022 (J.A.Appx7292-7294), i.e., before close of discovery on December 9, 2022, and before district court's order barring the requests was issued on December 16, 2022 (App.44a-45a), improperly, because District Court cannot contradict federal rules (28 U.S.C. §2071 and FRCP 83). (App.113a-115a; App.195a-197a).

Petitioner's requests for discovery extension before the close of discovery on December 9, 2022, were made in state of emergency (illness among her experts and paper motions would have been further delayed from mail delays during Holidays). That was "excusable neglect" for formal motion filed on December 14, 2022. (App.113a-116a; App.196a). Not finding "excusable neglect" (App.23a; App.48a-49a) is manifest injustice. *Symbionics Inc. v. Ortlieb*, 432 F. App'x 216, 220 (4th.Cir.2011).

Petitioner fully engaged in discovery August-December 2022 and demonstrated good cause that schedule cannot be met despite diligence (J.A.Appx8222-8223). Bottleneck was created by expert reports' timeline, illnesses, and paper filing delays during Holidays. Contra allegations (App.24a) earlier service of Petitioner's written discovery requests would not change that deposition of Respondents' expert could only be taken after his report was rebutted on December 9, 2022. In extreme unfairness, discovery enlargement stemming from medical emergency among Petitioner's experts was granted to Respondents but denied to Petitioner. (App.115a-118a; App.196a-197a).

District court's orders of December 16 and 30, 2022, barring extension of time requests for discovery without formal motion (App.44a-47a), contravene FRCP 6(b)(1)(A), 16(b)(4), and *Lujan* n.5. Federal Circuit violated this Court's precedents and failed to

review without deference district court's establishing of new legal principle (App.23a-26a). *Fitzpatrick v. Bitzer*, 427 U.S. 445, 449-50, 456 (1976).

Petitioner asserted constitutional right to equal access to justice and fair proceedings, not to electronic filing contrary to Federal Circuit. (App.25a-26a; App.110a-113a; App.193a-195a).

Differentially requiring paper filings from Petitioner reduced her discovery time by about 10% unfairly affecting the outcome. During the scheduled pre-trial discovery period, the approximately 12-day cumulative usurpation of her time from paper filings unfairly affected the outcome progressively delaying chain of substantive matters:

- precluded Petitioner's timely completion of discovery—which could only be done August 10, 2022-December 9, 2022;
- impeded her full opposition to motion for summary judgement (MSJ)—which could only be done after January 20, 2023, filing of MSJ; and
- delayed the filing of her motion for SAC for proper relief on merits—which could only be done after January 20, 2023, to aggregate new facts and circumstances from discovery and MSJ, which was in progress in November 2022.

(App.110a-113a; App.193a-195a).

Petitioner pleaded Federal Circuit "must reverse and remand with an order to enlarge discovery by 60 days, or as considered just and reasonable," (App.118a; App.195a) for fair proceedings. *Snyder v. Com. Of Mass.*, 291 U.S. 97, 116, 137 (1934); *Newell Co. v. Kinney Mfg. Co.*, 864 F.2d 757, 765 (Fed.Cir.1988); *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 546-548, 552-553 (1985). Federal Circuit refused to hear the Petitioner. (App.25a-26a).

(2) *Lower Courts Refused to Hear That Petitioner Asserted Respondents' Expert Testimony as Inadmissible and Challenged His Principles and Methodology*

Petitioner repeatedly asserted inadmissibility of Harris testimony, including challenging his principles and methodology and sufficiency of facts, in addition to bias. Allegations to the contrary are disingenuous. Appellant presented strong grounds for inadmissibility with about 33-page briefing and 500-page evidence. (App.118a-126a; 198a-201a).

Quotations from briefing:

"Dr. Harris offers little opinions on any factual dispute in this case because he massively reconstructs the prior art, and the legal opinions he offers are irrelevant and wildly unreliable. He has imposed his own interpretation of the law as to assessment of priority, claim interpretation, obviousness, unexpected results, and secondary considerations. Thus, consideration of Dr. Harris' testimony would waste time and create confusion. The testimony would also result in prejudice, as the testimony seeks to sow confusion about Plaintiff's disclosure, state of the prior art, and the law." (J.A.Appx7304).

"His methods are highly unreliable: So unreliable, that he failed to read the US Application no. 13/877,847 [] and rendered his opinion without reading the application. So unreliable, that he has contradicted his own recently published statements versus the statements he gave in his testimony. So unreliable, that he has contradicted his own statements within his testimony. So unreliable, that he has failed to read the cited art. So unreliable, that he has fabricated legal conditions to support Defendants' rejections. Thus, Dr. Harris'

testimony fails [to] meet each and every standard of the Federal Rules of Evidence ("FRE") 702(a)-(d) and is of no help to this Court."
(J.A.Appx8241).

"Dr. Harris' opinions and testimony lack any indicia of admissibility under *Daubert* and the Federal Rules of Evidence 104, 403, 405, 406, and 702. Indeed, if this Court performs its accurate gatekeeping role, Dr. Harris should be excluded because he is not qualified to serve an expert witness in this case, and his opinions and testimony are neither reliable nor probative of any of the issues in this case."
(J.A.Appx8242-8243).

Supporting Evidence:

Excerpts to Harris publications demonstrating contradictions in his testimony with his prior published statements including that relative dosages of omega-6 fatty acids and antioxidants including polyphenols are poorly understood even after USPA'847 filing in 2010.
(J.A.Appx7669-7714).

Unreliability in methodology that Harris massively culled prior art demonstrated by correction to Harris' Prior Art Tables.

(J.A.Appx8264-8292; S.Appx8264-8271).

Thus, Federal Circuit statement, "none of her challenges are to the evidence's admissibility" is false. (App.27a). Lower courts refused to hear the Petitioner and issued bogus decisions. (App.26a-27a; App.52a).

Lower courts committed harmful legal errors in failing to make relevancy and reliability determinations despite Petitioner's challenges to Harris' principles and methodology, sufficiency of

facts and data, and analytical gaps, required by Fed.R.Evid.702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 (1993) and by Advisory Committee on Rules and appellate courts. See each of *Daubert* 592, *Sardis v. Overhead Door Corp.,* 10 F.4th 268, 279, 282-283, 290 (4th.Cir.2021), *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997), and *Wickersham v. Ford Motor Co., 997 F.3d 526, 531 (4th.Cir.2021).*

Further, District Court weighed and relied on Harris testimony in summary judgement (App.63a) violating FRCP 56(c)(2) and *Tolan* 1866, and Federal Circuit affirmed it without meaningful review (App.26a-27a).

(3) *Federal Circuit Refused to Hear SAC Was Filed* ***Within Six Weeks*** *of MSJ Responded to* ***New*** *Issues in MSJ; Judgment for Respondents Was Entered* ***After*** *SAC Was Filed* ***Without*** *Considering SAC—Opinion* ***Conflicts*** *with This Court's and Fourth Circuit Precedents*

District Court first granted Respondents' January 20, 2023 MSJ, on March 30, 2023, without considering SAC filed on March 15, 2023 (App.99a) and the underlying facts and circumstances relied upon by the Petitioner for proper relief on merits including from new §101 and §103 rejections and citations in MSJ (App.53a-65a), then the very next day on March 31, 2023, denied the motion to file SAC in one sentence without justifying reasons (App.66a).

Federal Circuit refused to hear Petitioner's arguments and evidence of no delay and no prejudice to Respondents because the amendments sought in SAC derive from: matters already contained in some form in FAC, evidence on administrative record and from discovery, and new §101 and §103 rejections and citations raised in MSJ filed six weeks earlier, and no

futility. (App.27a; App.126a-130a; App.201a-203a; J.A.Appx13897-13909).

Federal Circuit's affirmation of the denial of SAC entry conflicts with FRCP 15(a)(2) and many of this Court's and Fourth Circuit precedents, including *Foman v. Davis*, 371 U.S. 178, 182 (1962); *Edwards v. City of Goldsboro*, 178 F.3d 231, 240-243 (4th.Cir.1999); *Pittston Co. v. U.S.*, 199 F.3d 694, 705 (4th.Cir.1999); *Johnson v. Oroweat Foods Co.*, 785 F.2d 503, 509 (4th.Cir.1986); *Mayfield v. National Ass'n for Stock Car Auto Racing, Inc.*, 674 F.3d 369, 379 (4th.Cir.2012); and *Matrix Capital Mgmt. Fund, LP v. BearingPoint, Inc.*, 576 F.3d 172, 193 (4th.Cir.2009), each of which instruct reversal of denial of SAC entry under similar circumstances.

There is no prejudice to Respondents because Petitioner had challenged the improper close of discovery, where she has been deprived of right to take deposition (App.201a-203a). *Mayfield* 379.

FRCP 15(a) mandate to freely give leave to amend, and cases should be decided on merits instead of disposing them on technicalities has been repeatedly upheld. *Foman* 182, *Edwards* 242, *Pittston* 705; *Johnson* 509, *Mayfield* 379, and *Matrix* 193.

Moreover, "improper denial of a 15(a) motion is sufficient grounds for [vacating the judgment]", as here, because the judgment for Respondents was improperly entered by district court while SAC was pending, then SAC was improperly denied entry the next day without justifying reasons. *Mayfield* 379, *Matrix* 193, and *Foman* 182. Fourth Circuit reversed denial of amendments to complaint requested 17 months after the original complaint was filed and after original complaint had been dismissed. *Edwards* 240-243.

(4) *Federal Circuit Refused to Recognize 28 U.S.C. §1331 Expressly Provides for Money Damages Against United States Without Limitation on Amount and Refused to Uphold Self-Executing Waiver of Sovereign Immunity for Fifth Amendment Constitutional Provisions*

28 U.S.C. §1331 expressly provides,

> "The district courts shall have original jurisdiction of *all* civil actions arising under the Constitution, laws, or treaties of the United States."

Editorial Notes to §1331 expressly state:

> "1980—Pub. L. 96–486...struck out minimum amount in controversy requirement of $10,000...in actions brought against the United States, any agency thereof, or any officer or employee thereof in an official capacity."
>
> (App.261a-217a).

Thus, §1331 expressly confers jurisdiction upon district courts to try *all* civil actions arising under the Constitution, laws, or treaties of the United States," and Editorial Notes to §1331 expressly specify the statute is legislated to include "actions brought against the United States, any agency thereof, or any officer or employee thereof in an official capacity" without limitation on the amount in controversy. Accordingly, district court has jurisdiction for the subject action arising from conspiracy and bad faith deprivation of constitutionally protected rights to discoveries under Article I, Section 8, Clause 8 and resulting injuries to Petitioner's life and business from violation of due process of law and Taking of Petitioner's property without just compensation under the Fifth Amendment.

The waiver of sovereign immunity for "These Fifth Amendment cases" under §1331 is *self-executing*, as

confirmed by *United States v. Testan*, 424 U.S. 392, 401 (1976), *Jacobs v. United States*, 290 U.S. 13, 16 (1933), *First English Evangelical Lutheran Church v. Cnty. of Los Angeles*, 482 U.S. 304, 314-316 (1987) and *San Diego Gas & Elec. Co. v. City of San Diego*, 450 U.S. 621, 654 (1981). "[t]he fact that the purely monetary aspects of the case could have been decided in the Claims Court is not a sufficient reason to bar that aspect of the relief available in a district court," finding district court has jurisdiction for monetary relief under §1331. See *Bowen v. Massachusetts*, 487 U.S. 879 n.48 (1988) (6-3 Opinion).

Federal Circuit opinion (App.28a-30a) disregarded the forgoing arguments (App.102a-107a; App.188a-190a).

(5) *Lower Courts Refused to Recognize FRCP 8(a)(2) and (e), Bell Atlantic, and Ashcroft Mandate for a Short Statement of Claim Construed to do Justice*

Regarding FRCP 12(b)(6) dismissal of causes of action by District Court to declaratory/injunctive relief, and claims to invasion of constitutionally protected patent rights, and misconduct and false statements made by USPTO, Petitioner asserted FAC abundantly states facts at ¶¶ 2–3, 11, 13, 36–37, 40–41, 45–46, 48–49, 55, and 56–63, n.6, Prayer for Relief (b)-(d), and (f) (J.A.Appx298-318), including refusal to hear Petitioner and refusal to enter evidence on record (see Statement of Case, B-D, *supra*), and that FRCP 8(a)(2) and (e) require nothing more than a "short and plain statement of the claim showing that the pleader is entitled to relief," "Pleadings must be construed so as to do justice," *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 556 (2007) "plausible grounds [] does not impose a probability requirement at the pleading stage; it simply calls for enough fact to raise a

reasonable expectation that discovery will reveal evidence," and *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009), "court can draw reasonable inferences from pleadings for the alleged misconduct." (App.107a-109a; App.190a-192a).

Lower courts refused to hear the Petitioner and violated this Court's instructions to construe pro se pleadings liberally, *Estelle v. Gamble,* 429 U.S. 97, 106 (1976) and construed pro se Petitioner's pleadings more stringently than attorneys'. (App.30a.-31a; App.37a-43a).

(6) *Lower Courts Refused to Recognize Seventh Amendment, FRCP 38, 39, 28 U.S.C. §1861, and Jarkesy Right to Jury Trial*

The U.S. Constitution Seventh Amendment, FRCP 38, 39, and 28 U.S.C. §1861, language puts forth right of trial by jury not as suggestion but a *requirement*, when demanded. Suits against government for money are commonly tried by jury. *Law v. United States*, 266 U.S. 494, 496 (1925); *Hepner v. United States*, 213 U.S. 103, 115 (1909); *United States v. Regan*, 232 U.S. 37, 47 (1914).

In *SEC v. Jarkesy*, 603 U.S.____ (2024) (Slip Op. at 3, 22) this Court affirmed Seventh Amendment right to jury trial against government, where matter cannot be resolved outside of an Article III court.

Similarly, present suit pertains to bad faith deprivation of patent rights and in addition to patent grant, seeks damages from due process violations and taking from regulatory delay. It can only be resolved in an Article III court, and Seventh Amendment right to jury trial applies, even if it is against government.

Federal Circuit disregarded (App.31a) the foregoing arguments (App.109a-110a; App.192a-193a).

(7) *Lower Courts Refused to Recognize FRCP 56(b), 56(c), 56(d)(2), Celotex, Harrods, Tolan, Jacobs, Markman, and Berkheimer in Premature Summary Judgment*

In denying Petitioner's Motion to Strike, Deny, or Stay Respondents' premature MSJ (J.A.Appx9858-9864; J.A.Appx9910-9914) and granting Judgement in favor of Respondents (App.53a-65a) District Court violated:

i. FRCP 56(b), 56(c), 56(d)(2), *Celotex* 322, and *Harrods Ltd. v. Sixty Internet Domain Names*, 302 F.3d 214, 244 (4th.Cir.2002) because close of discovery is under appeal.

ii. FRCP 56(c)(2), *Tolan* 1866, and *Jacobs v. N.C. Admin. Office of the Courts,* 780 F.3d 562, 568-569 (4th.Cir.2015) in weighing and relying upon Harris testimony challenged as inadmissible.

iii. *Markman* 517 U.S. 370, 387, and *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1370 (Fed.Cir.2018) because claim construction hearing was not held for legal determination of whether claims at issue perform well-understood, routine, and conventional activities to a skilled artisan, a genuine issue of material fact.

iv. Rule 56 and Celotex 322-26 mandate in failing to consider disputed facts in all materials responses and replies. Petitioner's briefing asserted:

"record is rife with other facts that are in serious dispute (see Dkt. 13, 66, 66.2, 66.3, 66.4, 69.13, 74.1, 74.2, 76)." (J.A.Appx9861).

"pending claims [] expressly disclaim natural products such as almonds, and indisputably meet the requirements of...§101...The Amended Complaint (Dkt. 13 [J.A.Appx297-319]) asserts that the features in the '847 application remain poorly understood at ¶¶ 6-8, 10, 25-28, and 31,

> which is also asserted in expert reports and rebuttals (Dkt. 57.1, 66.1, 66.2, 66.3, 66.4, 74.1, and 74.2). Accordingly, clearly there is a dispute in the present case as to both the claim interpretation and whether they are directed to well-understood, routine, and conventional activities." (J.A.Appx9912).
>
> District Court admitted to disputed facts, "Plaintiff asserts that Morris teaches away because its examples contain no or low amounts of omega-6 fatty acids and its antioxidant range," (App.63a).

Petitioner asserted, summary judgement must be vacated per *Celotex* 322-26 mandate because pleadings, expert opinions, show there are many disputed material facts. The evidence must be viewed in the light most favorable to nonmovant, *Poller* 473, and doubts resolved in her favor, *Cantor* 582. (App.136a).

Federal Circuit disregarded (App.32a-33a) the foregoing arguments (App.130a-137; App.203a-205a).

(8) *Federal Circuit Violated Due Process in **Entirely** Disregarding 34 Claims*

In extreme due process violation, besides claim 82, Federal Circuit entirely disregarded 34 claims, 7 independent, 17 product, 16 method, and 1 machine claim(s), despite Petitioner's objections to representative claim approach, violating *Shelcore, Inc v. Durham Industries, Inc.,* 745 F.2d 621, 624 (Fed.Cir.1984); *Altoona Publix Theatres v. American Tri-Ergon Corp.,* 294 U.S. 477, 487 (1935). (App.171a; App.184a-185a).

(9) *Federal Circuit Violated Tolan & Weisgram in Failing to Enter Judgement for Petitioner*

Impermissible reliance upon Harris testimony in granting the summary judgement (App.63) alone warrants vacation of the judgment and entry in Petitioner's favor. *Tolan* 1866 and *Weisgram* 453–56. (App.132a-133a; App.142a; App.150a-151a).

CONCLUSION

Lower courts obstructed innovation in nutrition arts by deviating from established judicial processes. Instead of liberally interpreting pro se submissions per *Estelle*, they imposed extrajudicial requirements on the Petitioner, necessitating this Court's supervisory intervention (Rule 10). This petition addresses issues crucial to the national interest, challenging judicial integrity and legal standards in patent disputes. Granting it would guide lower courts and uphold constitutional advancement standards.

February 26, 2025, Respectfully submitted,

/s/ Urvashi Bhagat
Urvashi Bhagat
Pro Se Petitioner