APPENDIX

APPENDIX TABLE OF CONTENTS

FEDERAL CIRCUIT

EASTERN DISTRICT OF VIRGINIA

THE UNITED STATES CONSTITUTION, STATUTES and TREATIES

NOTE: This disposition is nonprecedential.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

URVASHI BHAGAT,
Plaintiff-Appellant

v.

UNITED STATES PATENT AND TRADEMARK OFFICE, KATHERINE K. VIDAL, IN HER OFFICIAL CAPACITY AS UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE, UNITED STATES,
Defendants-Appellees

2023-1545

Appeal from the United States District Court for the Eastern District of Virginia in No. 1:20-cv-01515-CMHIDD, Senior Judge Claude M. Hilton.

Decided: April 3, 2024

URVASHI BHAGAT, Palo Alto, CA, pro se.

MAUREEN DONOVAN QUELER, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, for defendants-appellees. Also represented by OMAR FAROOQ AMIN, MARY L. KELLY, THOMAS W. KRAUSE, FARHEENA YASMEEN RASHEED; JESSICA D. ABER, MATTHEW JAMES MEZGER, Office of the United States Attorney for the Eastern District of Virginia, United States Department of Justice, Alexandria, VA.

Before PROST, CLEVENGER, and CUNNINGHAM, *Circuit Judges.*

PER CURIAM.

Urvashi Bhagat ("Bhagat") appeals several orders from the United States District Court for the Eastern District of Virginia: requiring Bhagat to file paper motions to the court, rejecting her requests for discovery enlargement and rescheduling of the pretrial conference, denying her request to file a second amended complaint, denying her request to exclude an expert, granting defendant United States Patent and Trademark Office's ("PTO") partial motion to dismiss Bhagat's causes of action unrelated to patentability, denying her request to strike the PTO's motion for summary judgment and granting that motion finding that Bhagat's patent claims are ineligible under 35 U.S.C. §§ 101 and 103. Bhagat also asserts various due process violations against the district court. We *affirm.*

BACKGROUND

A. The Patent Application

Bhagat is the inventor of the United States Patent Application No. 13/877,847 (the "Application"). The Application claims are directed to nutritional formulations containing omega-6 fatty acids and antioxidants, which the Application describes as contained "in any orally acceptable form, including, capsules, tablets, liquid formulations, or whole foods" and administered orally. The Application claims a "packaged product" where "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," and the dosage ranges "from 1 to 40g of omega-6 fatty acids and from 25mg to 10g of antioxidants . . . wherein the antioxidants comprise one or more polyphenols in the dosage of greater than 5mg." App. Br. to PTO at 46, claim 82. The Application also claims the product in a "kit" that includes a range of two to twenty different nutritional formulations, "which collectively provide an amount of nutrients from 0.0001 to 100 g/kg body weight . . . 40-80% of individual's daily calories . . . 10-50% calories from protein, 15-50% calories from lipids, and 35-85% calories from carbohydrates; and/or . . . deliver at least 50% of daily micronutrients for the individual" and/or is made up of "at least one of: vegetable or vegetable juice packs, fruit or fruit juice packs, dry grain packs, cereal packs, legume, grain, nuts, or seed packs, meat or seafood packs, or herbs, lipids, meals, snack, side dish, salad, desserts, milks, powder, puree, or yogurt packs." App. Br. to PTO at 23–4, claim 95.

The Application also contains method claims, wherein claim 88 sets out steps for "administering the dosage to an individual, wherein the individual belongs to a diet cohort" based on factors like "gender, age, genetic profile, family history, climactic temperature, or medical condition," claim 97 describes a method for treating "a medical condition or disease in the individual" and claim 116 recites a method for treating a variety of conditions such as aging, mental disorders, diabetes, autoimmune and infectious diseases. App. Br. to PTO at 21, 24, 31–32, claims 88, 97, and 116. None of the method claims, however, "include tailoring the nutrient dosages in the product to the diet cohort or restricting the total daily intake of any of the claimed nutrients." J.A. 21.

The Application additionally includes a withdrawn claim directed to a computer system to implement the method claims and to output nutritional plans for individuals based on dietary preferences and guidelines "wherein the nutrition program comprises a listing of formulations, optionally comprising food items, wherein from 1 to 40g of omega-6 fatty acids and from 5mg to 10g of antioxidants comprising at least 5mg of one or more polyphenols are included in the program for daily consumption by the individual." App. Br. to PTO at 29–30, claim 112.

B. Procedural History

1. PTO Proceedings

Bhagat filed the Application with the PTO in 2013. The PTO examiner rejected all pending claims of the Application for obviousness and rejected claims 82 and 99 for failing to comply with the written

description requirement, claims 82, 87, 91–93, 96, 97, 99, 102, 109, 110, and 113–120 for indefiniteness, and claims 88, 89, 95, 103, and 107–110 for improper dependency.

Bhagat appealed to the Patent Trial and Appeal Board ("Board"), which reversed the rejection for written description and affirmed the rejection for obviousness on the merits.[1] The Board affirmed the obviousness rejection because the Application claims were "obvious in light of numerous past expert studies and disclosures," particularly Claudia R. Morris's U.S. Published Patent Application Number 2008/0213239 ("Morris"). *Bhagat v. U.S. Pat. & Trademark Off.*, No. 1:20-cv-1515, 2023 WL 2721003, at *2 (E.D. Va. Mar. 30, 2023) ("Summary Judgment Opinion").

The Board explained that Morris addresses the treatment of various conditions, like cardiovascular disease, by disclosing nutritional formulations comprising omega-6 fatty acids and Vitamin E in dosages and amounts that overlap with those in the Application claims. *Id.* at *2 ("Morris shows that the formulations comprise from about 50 mg to about 500 mg omega-6 fatty acids that may be administered once, twice, or three times daily, which would equal a dosage ranging from 50 mg to 1,500 mg of omega-6 fatty acids a day."). The Board also found that Morris disclosed packaged formulations of omega-6 fatty acids, Vitamin E, and polyphenols, as well as dosages

[1] The Board summarily affirmed the rejections based on indefiniteness and improper dependency because Bhagat failed to include in her Appeal Brief any substantive arguments on the merits that the rejections on those grounds should be reversed. J.A. 5980, 6480.

of omega-6 and Vitamin E in the ranges claimed in the Application claims and disclosed that "dosages are a result-effective variable and may be optimized for an individual," rendering the Application's claimed dosages obvious. *Id.* Factors discussed in Morris as impacting the preparation of formulations include age, weight, and genetic makeup, which overlap with the diet cohort factors in the Application. *Id.* at *2. The Board found that Morris disclosed most of what the claimed invention covered, and that the only difference— that the Application disclosed using nutrients from different sources—was rendered obvious from other expert disclosures teaching the mixtures of different nutrient sources. *Id.* at *2 ("The only difference the Board found between Morris and [the Application's] claimed formulation was an explicit disclosure of using nutrients from different sources . . . . [which] would have been obvious in light of another expert's teachings of oil blends from different sources.").

2. District Court Proceedings

On December 10, 2020, Bhagat filed suit in the United States District Court for the Eastern District of Virginia to challenge the Board's decision, alleging that the district court had jurisdiction pursuant to 35 U.S.C. § 145 and 28 U.S.C. §§ 1331, 1338(a), and 1361. *Id.* at *2. Bhagat amended her complaint on April 19, 2021. Am. Compl., *Bhagat v. USPTO*, (No. 1:20-cv-01515), ECF 13. In addition to alleging that the PTO erroneously rejected her patent claims, Bhagat asserted entitlement to general damages due to the PTO's "bad faith," and asserted causes of action for "taking of her property, including but not limited to her patent," tortious harassment, and a mandamus

compelling the PTO to issue the Application's rejected patent claims. Am. Compl. at ¶¶ 64–84, *Bhagat v. USPTO*, (No. 1:20-cv-01515), ECF 13; *Bhagat v. U.S. Pat. & Trademark Off.*, No. 1:20-cv-1515, 2021 WL 3130866, at *2 (E.D. Va. July 22, 2021) ("Motion to Dismiss Opinion").

On July 22, 2021, the district court granted the PTO's motion to dismiss all of Bhagat's causes of action that were not related to the patentability of the Application claims and to strike Bhagat's request for a jury trial. *Motion to Dismiss Opinion*, 2021 WL 3130866, at *3.

The district court first determined that it did not have subject matter jurisdiction over the claims for takings, money damages, or tortious harassment due to sovereign immunity. *Id.* at *1. As the district court noted, agencies of the United States, such as the PTO, are generally shielded from liability by sovereign immunity unless Congress has expressly waived it. *Id.*

The district court explained that "Congress has not waived its sovereign immunity for money damages in actions brought pursuant to 35 U.S.C. § 145" and therefore found it did not have jurisdiction over any of Bhagat's claims for money damages under Section 145. *Id.*

The district court then stated that the Tucker Act waives sovereign immunity for claims for non-tort money damages, such as takings claims, but gives exclusive jurisdiction to the Court of Federal Claims when those damages are over $10,000, and that the Federal Tort Claims Act waives sovereign immunity for tortious harassment only if a plaintiff first

presents an administrative claim to the agency that the plaintiff purports is responsible for their injury. *Id.* at *1–2. Since Bhagat brought claims for $500,000,000 against the United States, the district court concluded that the Court of Federal Claims had exclusive jurisdiction over the damages claim under the Tucker Act. *Id.* at *1. The district court also found that since Bhagat did not present an administrative claim to the PTO, the agency allegedly responsible for harassing her, the district court did not have jurisdiction over her tortious harassment claim. *Id.* at *2.

Next, the district court addressed the PTO's motion to dismiss for failure to state a claim on which relief could be granted, finding that there were no facts in the Amended Complaint to support Bhagat's allegations that the PTO violated her constitutional rights, made false statements, or that she was entitled to mandamus relief. *Id.* The district court found that Bhagat failed to establish, as required for mandamus relief, that "(1) she has a clear right to the relief requested and (2) no other relief is available" because she failed to plausibly allege that the PTO owes her a duty to issue her patent and because she had another avenue of relief under Section 145, which she also asserted in her Amended Complaint. *Id.* (citing *Heckler v. Ringer*, 466 U.S. 603, 616 (1984)). The district court also concluded that Bhagat alleged only that the PTO erred in adjudicating her patent without alleging any facts to support her claim that the PTO made false statements and acted with misconduct, and therefore concluded that she made only "naked assertions" that could not survive the PTO's motion to dismiss. *Id.* (citing *Ashcroft v. Iqbal*,

556 U.S. 662, 678 (2009)). Similarly, the district court found that Bhagat's allegation that the PTO violated her constitutional rights was not a plausible claim because she identified neither the violative action the PTO allegedly took nor the constitutional right it purportedly violated. *Id.* at *3.

Finally, the district court granted the PTO's motion to strike Bhagat's request for a jury trial because the Seventh Amendment right to a jury trial is not applicable in actions against the United States, unless Congress in waiving sovereign immunity unequivocally expresses that the right exists in the authorizing statute. *Id.* The district court held that the remaining patent claim, for which Congress waived sovereign immunity under Section 145, did not provide Bhagat with a right to a jury trial because Section 145 contains no unequivocal right to a jury trial. *Id.*

Thus, the district court dismissed all causes of action besides the patent claim under Section 145 and struck Bhagat's request for a jury trial. *Id.*

On December 14, 2022, Bhagat filed a motion for the extension of time for expert rebuttal reports and the enlargement of discovery, arguing that the PTO's "longwinded and disjointed" expert reports required more time to prepare the rebuttals, that illness and unavailability of her experts caused a delay, and that she contacted the judge's law clerk by phone and email to request a conference to extend time for expert rebuttals and enlarge discovery before the close of discovery.[2] Mot. for Extension of Time for Expert

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[2] Per her own admission, Bhagat contacted the clerk multiple times from November 20, 2022, through December 5, 2022. ECF

Rebuttal Report & Further Enlargement of Discovery, *Bhagat v. USPTO*, (No. 1:20-cv-01515), ECF 62, 64. Bhagat requested an extension of time for disclosing rebuttals to the PTO's experts to December 9, 2022, the date that she did submit the rebuttals, which was thirteen days after the initial deadline of November 25, 2022. ECF 64, at 11. She also requested that discovery be enlarged to February 6, 2023, to allow her further discovery requests and to permit her to depose the PTO's expert witness, and for the final pretrial conference to be delayed from January 12, 2023, to February 12, 2023. ECF 64, at 11.

Also on December 14, 2022, Bhagat filed a motion to disqualify the PTO's expert, Dr. William S. Harris, as an expert witness due to "numerous conflicts of interest, and his opinions and testimony [being] neither relevant nor reliable pursuant to the standards set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 506 U.S. 579 (1993)." Mot. to Disqualify Dr. Harris at 1, *Bhagat v. USPTO*, (No. 1:20-cv01515), ECF 66.

On December 16, 2022, the district court issued an order addressing Bhagat "constantly emailing and calling the [c]ourt requesting various forms of relief despite being informed by the [c]ourt, on more than one occasion, that written motions are the only appropriate form by which to request relief from the [c]ourt." *Bhagat v. U.S. Pat. & Trademark Off.*, No. 1:20-cv-01515, 2022 WL 18401639, at *1 (E.D. Va. Dec. 16, 2022), ECF 68 ("First Ex Parte Communications Order"). The district court noted

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64, at 6. The district court subsequently issued orders explaining that this was not the proper mode for requesting relief from the court, discussed *infra* at 8–9.

that, while it had granted Bhagat's motion for Pro Se E-Noticing, that grant did not permit her to "file documents or requests for relief electronically" and that she must follow the proper procedure for requesting relief, which is "filing a paper copy of any motion through the Clerk's Office that includes the relief requested and a legal basis for granting such relief." *Id.* The district court directed Bhagat to review the United States District Court for the Eastern District of Virginia Pro Se Reference Handbook and asserted that it would not respond to any further email or phone communications from Bhagat. *Id.*

In response, Bhagat filed a motion, which the district court "interpret[ed] . . . as a Motion to Vacate the December 16, 2022 Order." *Bhagat v. U.S. Pat. & Trademark Off.*, No. 1:20-cv-01515, 2022 WL 18401638, at *1 (E.D. Va. Dec. 30, 2022), ECF 75 ("Second Ex Parte Communications Order"). The district court denied this motion on December 30, 2022, reiterating that Bhagat "should never contact chambers regarding any substantive issues concerning the case unless authorized by the [c]ourt in advance" and concluding that Bhagat's substantive request for extension of time for expert rebuttal reports, which was the topic of her ex parte communication, was not an exception to this rule just because the district court had the "ability to sua sponte grant an extension of time 'with or without motion or notice' as noted" in Federal Rule of Civil Procedure 6(b)(1)(A). *Id.*

On January 10, 2023, the district court denied Bhagat's motion to enlarge discovery to February 6, 2023, and to reschedule the pretrial conference, but

granted the motion in part to permit the extension of the rebuttal disclosures to December 9, 2022. Order on Mot. for Extension of Discovery, *Bhagat v. USPTO*, (No. 1:20-cv-01515), ECF 77. The district court reasoned that Bhagat's motion, which she filed after the close of discovery, was not timely, and that regardless she failed to show good cause for an extension because her delays were caused by her own legal strategy[3] and inability to manage her personal workload. *Id.* The district court found that, since Bhagat did not begin discovery until November 1, 2022, despite discovery opening on August 11, 2022, she did not show good cause for her extension request. *Id.* The district court was also unpersuaded by Bhagat's arguments that the PTO has more resources than she does, as it noted there is often a disparity in resources among parties. *Id.* Thus, it rejected her request to extend discovery or to reschedule the pretrial conference. *Id.*

On January 17, 2023, the district court denied Bhagat's motion to disqualify Dr. Harris, reasoning that her "objections go to the weight of the expert's testimony, not admissibility." Order Declining to

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[3] Bhagat filed a petition to the United States Supreme Court requesting that the Supreme Court issue a writ of mandamus to the United States District Court for the Eastern District of Virginia on August 17, 2022. *In re Urvashi Bhagat*, 2022 WL 4226537 (August 17, 2022). Her Petition was denied on October 31, 2022. *In re Bhagat*, 143 S. Ct. 396 (2022). The district court determined that Bhagat's decision to wait to begin discovery until after the outcome of her petition to the Supreme Court was a legal strategy that did not entitle her to an extension for discovery. Order on Mot. for Extension of Discovery, *Bhagat v. USPTO*, (No. 1:20-cv-01515), ECF 77.

Disqualify Dr. Harris, *Bhagat v. USPTO*, (No. 1:20-cv-01515), ECF 83.

The PTO filed a motion for summary judgment on January 20, 2023, arguing that the undisputed facts show that the Application claims are patent ineligible under 35 U.S.C. § 101 and that claims 82–89, 91–104, 107–110, and 113–120 are unpatentable as obvious under 35 U.S.C. § 103. On January 31, 2023, Bhagat responded with a motion to strike the PTO's summary judgment motion as premature since she had appealed the close of discovery, denial of the rescheduling of the pretrial conference, and admissibility of the PTO's expert report.

The district court denied Bhagat's motion to strike the PTO's motion for summary judgment and granted the PTO's motion, finding that the claims at issue are patentineligible under Section 101 and unpatentable under 103. *Summary Judgment Opinion*, 2023 WL 2721003, at *1–5.

The district court first addressed the motion to strike, finding that since Bhagat had over four months to conduct discovery, her argument that the motion for summary judgment was premature due to her appeal of the district court's refusal to extend discovery was not persuasive. *Id.* at *1. The district court also found that Bhagat failed to demonstrate that a stay was supported pending interlocutory appeal of discovery matters. *Id.*

After concluding that Bhagat's motion to strike the PTO's motion should be denied, the district court turned to the merits of the PTO's summary judgment motion.

The district court first addressed the PTO's argument that all the Application claims are patent ineligible under Section 101, finding that both the product and method claims were directed to patent-ineligible subject matter and were not transformed to patent-eligible subject matter because the only limitations beyond those directed at natural phenomena or abstract ideas were well-known and conventional. *Id.* at *3–4 (citing *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014)); *see also* PTO Mem. in Supp. of Summ. Judgment at 16–24, *Bhagat v. USPTO* (No. 1:20-cv-01515), ECF 86.

In its *Alice* step one analysis, i.e., determining whether the claims are directed to a patent-ineligible concept such as a natural phenomenon or abstract idea, the district court found that the Application claims recited a combination of nutrients naturally present in almonds, with some of the claims describing the same dosages of omega-6 fatty acids, polyphenols, and phytosterols contained in almonds. *Summary Judgment Opinion*, 2023 WL 2721003, at *3 ("[A]lmonds contain the dosages of omega-6 fatty acids recited in claims 92, 107, 113, and 119, and the polyphenol dosage recited in claim 120. Almonds further comprise phytosterols as required by claim 85, in the dosages recited in claims 86, 93, 108, and 114."); *see also id.* ("Claim 94's requirement that one formulation provide omega-6 fatty acids in a dosage less than 1 g, but that a plurality collectively provide 1 to 40 g of omega-6 merely encompasses a product of 100 g of almonds broken into 5 g increments. Almonds also contain the phytochemicals, lipids, antioxidants, vitamins, minerals, and fiber recited in claims 87 and 101 [and] claim 89 encompasses a

mixture of one or more food items, which includes a mixture of 100 g of almonds with other nuts."). The district court also found that claim 112, which "deals with a computer system that implements the method of preparing the product" was directed to the abstract idea of meal planning. *Id.* at *4.

In its *Alice* step two analysis, i.e., determining if any additional claim limitations transform a natural phenomenon or abstract idea into a patent-eligible invention, the district court concluded that all the remaining limitations recited well-known activities such as conventional packaging practices, crushing almonds into a powder, and "administering," "determining," "selecting," and "preparing" steps. *Id.* The district court found that the "administering" step included eating or feeding almonds to an individual and that the "diet cohorts" were identified in "a generic manner that all humans would qualify." *Id.* Similarly, the district court found that the "determining" step groups individuals into the broad diet cohorts "based on food preference, dietary habits, age, or gender" and that the "selecting" and "preparing" steps link the nutritional formulations to the diet cohorts. *Id.* The district court also concluded that claim 112 does nothing more than add conventional computer components to the abstract idea of meal planning. *Id.* Thus, the district court concluded the Application's claims were patent ineligible under Section 101.

The district court then found that the pending Application claims were further unpatentable as obvious under Section 103 considering the teachings of Morris, which the Board relied on in rejecting the claims, and Joshua C. Anthony et al., U.S. Published

Patent Application Number 2007/0166411 A1 ("Anthony"). *Id.* at *5. The district court noted that the Board determined that Morris taught "preparing and administering a packaged dietary formulation comprising omega-6 fatty acids, Vitamin E, and polyphenols" as well as "dosages of omega-6 fatty acids and Vitamin E overlapping the claimed range." *Id.* The district court also noted that the PTO's expert witness Dr. Harris explained that "the benefits of consuming the claimed nutrients were well-known in the art as of 2010" and that Bhagat had not argued how the references Dr. Harris used to support this statement did not disclose the limitations in the dependent claims. *Id.* The district court found that Bhagat failed to establish unexpected results to rebut the presumption of obviousness from the overlapping dosage ranges in Morris and the Application and could not support her contention that Morris teaches away from the Application claims. *Id.* Finally, the district court found that Bhagat's argument that the prior art was not relevant because it did not address the same problem solved by her Application claims was unconvincing because "the prior art [was] from the same field of endeavor in nutritional formulations." *Id.*

Therefore, the district court granted the PTO's motion for summary judgment that the Application claims were not eligible for patent protection. *Id.*

On March 15, 2023, Bhagat filed a motion for leave to file a second amended complaint, which the district court denied as unduly delayed on March 31, 2023. Mot. for Leave to File Second Am. Compl., *Bhagat v. USPTO*, (No. 1:20-cv-01515), ECF 113; Order

Denying Mot. to File Second Am. Compl., *Bhagat v. USPTO*, (No. 1:20-cv-01515), ECF 126.

Bhagat appeals (1) the district court's orders requiring her to file paper motions to request relief from the court, denying her request for the enlargement of discovery, denying her challenge to the admissibility of Dr. Harris's testimony, and denying her leave to file a second amended complaint, and alleges that the failure of the judges to recuse themselves was a violation of due process; (2) the district court's dismissal of her damages, takings, and misconduct claims and striking of her demand for jury trial; and (3) the district court's denial of her motion to strike, and its subsequent grant of, the PTO's motion for summary judgment. This Court has jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

This Court reviews district court orders on procedure, discovery, complaint amendments, judge recusal and the admissibility of evidence under the law of the regional circuit; here, the Fourth Circuit, which reviews these decisions for an abuse of discretion. *Panduit Corp. v. All States Plastic Mfg. Co.*, 744 F.2d 1564, 1574–75 (Fed. Cir. 1984); *United States ex rel. Nicholson v. MedCom Carolinas, Inc.*, 42 F.4th 185, 196 (4th Cir. 2022) ("District courts have inherent power to manage their dockets with an eye toward speedy and efficient resolutions . . . . So we review decisions about the nature of a dismissal . . . for an abuse of discretion."); *United States ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 290 (4th Cir. 2002) ("We afford substantial discretion to a district court in managing discovery

and review discovery rulings only for abuse of that discretion."); *Lone Star Steakhouse & Saloon, Inc. v. Alpha of Virginia, Inc.*, 43 F.3d 922, 940 (4th Cir. 1995) ("We review for abuse of discretion a district court's ruling on a motion for leave to amend and to add counterclaims."); *United States v. Cherry*, 330 F.3d 658, 665 (4th Cir. 2003) ("We review a trial judge's decision on matters of recusal for abuse of discretion."); *United States v. Crisp*, 324 F.3d 261, 265 (4th Cir. 2003) ("We review for abuse of discretion a district court's decision to admit or reject expert testimony.").

This Court also reviews procedural decisions that are not unique to patent law, such as dismissal of a complaint for lack of jurisdiction or failure to state a claim and a grant of summary judgment, under the law of the regional circuit. *Madey v. Duke Univ.*, 307 F.3d 1351, 1358 (Fed. Cir. 2002); *Weisner v. Google LLC*, 51 F.4th 1073, 1081 (Fed. Cir. 2022); *Syngenta Crop Prot., LLC v. Willowood, LLC*, 944 F.3d 1344, 1355 (Fed. Cir. 2019). The Fourth Circuit reviews dismissals under both FRCP 12(b)(1) and 12(b)(6) de novo. *Madey*, 307 F.3d at 1358 (citing *Evans v. B.F. Perkins Co.*, 166 F.3d 642, 647 (4th Cir. 1999)); *Burbach Broad. Co. of Del. V. Elkins Radio Corp.*, 278 F.3d 401, 405–06 (4th Cir. 2002). Similarly, the Fourth Circuit reviews the grant of summary judgment de novo, construing the evidence in the light most favorable to the non-moving party. *Syngenta*, 944 F.3d at 1355. The Fourth Circuit reviews district court determinations of whether summary judgment was premature for an abuse of discretion. *Harrods Ltd. v. Sixty Internet Domain Names*, 302 F.3d 214, 244 (4th Cir. 2002).

A. Non-Patent Claims

The district court did not abuse its discretion or violate due process in issuing its orders declining to extend discovery, requiring Bhagat to file motions to request relief and to do so via paper motions rather than through electronic filing, admitting Dr. Harris's testimony, or declining to allow Bhagat another amendment to her complaint. It was also not reversable error for Judge Claude M. Hilton and Magistrate Judge Ivan Davis to decline to recuse themselves. The district court did not err as a matter of law in dismissing Bhagat's claims for damages, takings, constitutional violations, and mandamus under FRCP 12(b)(1) and 12(b)(6).

1. Procedural Issues

Bhagat fails to demonstrate that the district court abused its discretion or violated due process in its management of discovery and the trial procedure.

First, it was not an abuse of discretion to deny Bhagat's request to extend discovery, which she filed after the close of discovery. Bhagat's argument that her ex parte emails and calls were an attempt to timely request the extension of discovery fails because the district court repeatedly notified Bhagat that the proper procedure for requesting relief from the court was through filing paper motions. *See, e.g.*, First Ex Parte Communications Order, *Bhagat v. USPTO*, (No. 1:20-cv-01515), ECF 68. Thus, Bhagat's actions did not amount to "excusable neglect" that could justify her untimely extension motion. *Symbionics Inc. v. Ortlieb*, 432 F. App'x 216, 219–20 (4th Cir. 2011) ("[A] district court should find excusable neglect only in the *extraordinary cases* where injustice would otherwise

result." (emphasis in original)). Further, the district court did not abuse its discretion in finding that Bhagat failed to demonstrate good cause to extend discovery because she waited three months from the opening of discovery to send her discovery requests. *Cook v. Howard*, 484 F. App'x 805, 815– 16 (4th Cir. 2012) (concluding that the district court did not abuse its discretion by failing to find good cause where the party demonstrated a lack of diligence by waiting months between filing suit and seeking discovery).

Second, the district court did not abuse its discretion by requiring Bhagat to file written motions to request relief orders, nor did it violate due process with its rule that pro se parties must submit written motions rather than electronic filings. The district court's local rule, E.D. Va. Local Civil Rule 7(F), requires that parties file written briefs with all motions to request relief from the court, and E.D. Va. Local Civil Rule 1(A) in conjunction with the E.D. Va. Electronic Case Filing Policies and Procedures Manual requires pro se parties to file using paper rather than through electronic filing. E.D. Va. Local Civ. R. 7(F), 1(A); U.S. Dist. Ct. E.D. Va., Electronic Case Filing Policies and Procedures Manual, at 12, 23 (Revised Sept. 23, 2020), https://www.vaed.uscourts.gov/sites/vaed/files/ECF-Manu al%2012-17-2021.pdf. Bhagat argues that Rule 7(F) conflicts with FRCP 6(b)(1)(A); however, that rule merely permits the court to grant extensions without motion and therefore does not conflict with the local rule's requirement that applies in the absence of such a discretionary exception. *See* Fed. R. Civ. P. 6(b)(1)(A); *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 896 n.5 (1990) (explaining that a court may,

using its *discretion*, grant a request for an extension of discovery even without motion or notice). In fact, under another local rule, the district court has discretion to waive the requirement for a written motion in some circumstances, which further demonstrates that the local rules align with the discretionary nature of FRCP 6(b)(1)(A). E.D. Va. Local Civ. R. 26(B).

Similarly, it was not a due process violation for the district court to require Bhagat to comply with its rule that pro se parties may not use electronic filing, because she has not identified that she has a "right" to electronic filing, nor has she established that she suffered lack of notice or opportunity to be heard. *See In re Hunter*, 600 F. App'x 126, 127 (4th Cir. 2015) ("[Plaintiff] cite[d] neither statutory law nor judicial precedent demonstrating a clear right to file electronically."); *J.G. Peta, Inc. v. Club Protector, Inc.*, 65 Fed. App'x 724, 728 (Fed. Cir. 2003) (finding no constitutional right to submit motions in a particular format); *Cleveland Bd. Of Educ. v. Loudermill*, 470 U.S. 532, 546 (1985) ("The essential requirements of due process . . . are notice and an opportunity to respond."). Bhagat alleges that the district court usurped approximately twelve days of her time by requiring paper filings, which led to her delay in completing discovery, impeded her ability to oppose summary judgment, and delayed her filing her motion to amend her complaint a second time. Appellant's Br. at 27. However, Bhagat's delays were primarily caused by her decision to wait three months to begin discovery and, similarly, she did not move for leave to file a second amended complaint until over a year and a half after her first amended complaint was partially

dismissed and after filing notice of appeal to this Court. *See* Order Granting Defendant's Partial Mot. to Dismiss Plaintiff's First Am. Compl., *Bhagat v. USPTO*, (No. 1:20-cv-01515), ECF 26 (07/22/2021); Mot. for Leave to File Second Am. Compl., *Bhagat v. USPTO*, (No. 1:20-cv-01515), ECF 113 (03/15/2023); Notice of Appeal, *Bhagat v. USPTO*, (No. 1:20-cv-01515), ECF 81 (01/13/2023). Thus, the district court did not violate due process by requiring Bhagat to file electronically where she has not shown any constitutional right to do so or by rejecting her argument that she had no notice or opportunity to be heard because of the district court's requirement.

Third, the district court did not abuse its discretion when it denied Bhagat's motion to exclude Dr. Harris's testimony because the district court correctly noted that Bhagat's complaints about Dr. Harris's testimony went to the weight, rather than admissibility, of that testimony. *See Bresler v. Wilmington Trust Co.*, 855 F.3d 178, 195–96 (4th Cir. 2017) (finding it was not an abuse of discretion for the district court to decline to exclude an expert's testimony under *Daubert* where the challenges to the testimony went to weight and credibility rather than admissibility). *Daubert* challenges should be to the reliability and relevance of the expert's principles and methodology rather than to the expert's conclusions. *Daubert v. Merrell Dow Pharma., Inc.*, 509 U.S. 579, 595 (1993). Bhagat did not challenge Dr. Harris's principles or methodology; rather, she sought disqualification based on his "significant financial interest" in preventing the Application from being granted and his purported misinterpretation of the prior art and the law. Mem. in Supp. of Mot. to

Disqualify Dr. Harris at 3, 7, *Bhagat v. USPTO*, (No. 1:20-cv-01515), ECF 66. Bhagat's argument of bias goes to Dr. Harris's credibility, and her argument that Dr. Harris mischaracterized the prior art and the law goes to the weight of his evidence; none of her challenges are to the evidence's admissibility and thus the district court did not abuse its discretion in denying her motion to exclude Dr. Harris's testimony.

Fourth, it was not an abuse of discretion for the district court to deny Bhagat's motion for leave to file a second amended complaint because she does not dispute that the motion was delayed and puts forth no evidence that her delay would not prejudice the PTO to permit her to amend her complaint after discovery had closed and judgment for the PTO entered. *See Mayfield v. National Ass'n for Stock Car Auto Racing, Inc.*, 674 F.3d 369, 379 (4th Cir. 2012) (finding the district court did not abuse its discretion in denying a motion to amend a complaint filed over two and a half years prior when significant discovery had occurred); *see also Matrix Capital Mgmt. Fund, LP v. BearingPoint, Inc.*, 576 F.3d 172, 193 (4th Cir. 2009) ("[T]he further the case progressed before judgment was entered, the more likely it is that the amendment will prejudice the defendant . . . .").

Fifth and finally, it was not reversable error for Judge Hilton and Magistrate Judge Davis to decline to recuse themselves from the case. Bhagat did not request that either judge do so at any point before the district court; thus, she raises this issue for the first time on appeal. The only arguments that Bhagat puts forth to establish that the judges were biased are that their rulings were all "substantially against" Bhagat and that "the court silenced [Bhagat] in hearing . . .

and pressed her to withdraw the action." Appellant's Br. at 66–67 (citing J.A. 9922–48; J.A. 9932). These arguments are insufficient to establish a substantial interest for either judge that would create a temptation that would lead the average judge to be biased. *Aetna Life Ins. Co. v. Lavoie*, 106 S. Ct. 1580, 1587 (1986); *see also Litkey v. United States*, 510 U.S. 540, 555 (1994) ("[J]udicial rulings alone almost never constitute a valid basis for a bias or partiality motion" and "judicial remarks during the course of a trial that are critical or disapproving of, or even hostile to, counsel, the parties, or their cases, ordinarily do not support a bias or partiality challenge.").

Thus, none of the district court actions in managing discovery or trial procedure constituted an abuse of discretion or a violation of the due process clause.

2. Dismissal

The district court did not err in dismissing Bhagat's damages, takings, and tortuous harassment claims for lack of jurisdiction or in dismissing her causes of action for misconduct, violation of a constitutional right, and entitlement to mandamus relief for failure to state a claim on which relief can be granted.

Bhagat's claim for general damages and her claim for damages under the Takings Clause are claims against the United States for money, which fall under the Tucker Act. 28 U.S.C. § 1491. The Tucker Act waives sovereign immunity by granting jurisdiction to the Court of Federal Claims over claims against the United States "for liquidated or unliquidated damages in cases not sounding in tort." *Id.* District

courts have concurrent jurisdiction over these claims only when the claims do not exceed $10,000; otherwise, the Court of Federal Claims has exclusive jurisdiction. *E. Enters. v. Apfel*, 524 U.S. 498, 520 (1998); *Suburban Mortg. Assoc., Inc. v. U.S. Dep't of Hous. & Urban Dev.*, 480 F.3d 1116, 1121 n.8 (Fed. Cir. 2007) (explaining that the Court of Federal Claim's exclusive jurisdiction for money damages over $10,000 comes from Congress not granting any other court jurisdiction over these claims and the "Little Tucker Act" that gives district courts concurrent jurisdiction over Tucker Act claims that do not exceed $10,000) (citing 28 U.S.C. § 1346(a)(2)).[4] It is undisputed that Bhagat seeks over $10,000 in damages; thus, the district court did not err in finding it lacked jurisdiction over her general damages claim and damages under the Takings Clause claim.

Similarly, there is no waiver of sovereign immunity for claims for money damages under 28

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[4] Contrary to Bhagat's contentions, this jurisdictional scheme has not been overruled by the Supreme Court, and the cases that Bhagat cites for this proposition do not support her argument. Appellant's Br. at 20–21 (citing *Knick v. Township of Scott*, 139 S. Ct. 2162, 2179 (2019) (removing the "state-litigation requirement" for takings claims against local governments that required the takings claim to be brought in state court before federal court); *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312–14 (2005) (finding federal question jurisdiction over a state law claim that involved contested issues of federal law); *Duke Power Co. v. Carolina Env't Study Grp., Inc.*, 438 U.S. 59, 71 n.15 (1978) (finding jurisdiction in a district court under Section 1331(a) where the party did not seek compensation for a takings claim, which the Court clarified would be properly brought in the Court of Claims, but instead requested a declaratory judgment).

U.S.C. §§ 1331, 1338, or 35 U.S.C. § 145 because none of these statutes contain express and unequivocal waivers of sovereign immunity. *United States v. Testan*, 424 U.S. 392, 399 (1976) (stating that waivers of sovereign immunity must be expressed unequivocally). Bhagat fails to point to an express waiver of sovereign immunity in any of the relevant statutes. Additionally, the PTO is not, as Bhagat contends, a "sue or be sued" agency that operates similarly to a private corporation, and there is no "sue or be sued" clause in the Patent Act. *See, e.g.*, 35 U.S.C. § 1.

The district court was also correct to dismiss Bhagat's allegations of misconduct, violations of constitutional rights, and entitlement to mandamus relief for failure to state a claim on which relief could be granted because none rise above conclusory allegations.

To support her argument that the district court erred in dismissing her claims for misconduct, constitutional violations, and entitlement to mandamus relief, Bhagat points to numerous portions of her Amended Complaint and essentially argues that she had a constitutional right to have her Application issue as a valid patent and that the PTO's refusal to do so was a result of its bad faith and misconduct. Appellant's Br. at 22 (citing Am. Compl. at ¶¶ 2–3, 11, 13, 36–37, 40–41, 45–46, 48–49, 55, and 56–63, Prayer for Relief (b), (c), (d), and (f)). The portions of the Amended Complaint that Bhagat points to merely critique the PTO for rejecting her claims and the PTAB for maintaining most of those rejections, and at no point does Bhagat identify specific false statements or actions of misconduct

from the PTO or cite to any portion of the Constitution to support the PTO's alleged violation of her constitutional rights. Further, for mandamus relief, Bhagat failed to plead that she had a clear right to have her Application issued as a valid patent and that there was no alternative relief available—particularly because Bhagat included claims for relief under § 145 in her complaint, acknowledging that alternative relief existed. Am. Compl. Prayer for Relief (c). Thus, the district court did not err in finding that Bhagat failed to state a claim on these issues.

Finally, Congress did not clearly provide a right to a jury trial in 28 U.S.C. §§ 1331, 1338, or 35 U.S.C. § 145, and thus the district court correctly struck Bhagat's request for a jury trial. *See Lehman v. Nakshian*, 453 U.S. 156, 160–63 (1981) ("[I]f Congress waives the Government's immunity from suit . . . the plaintiff has a right to a trial by jury only where that right is one of 'the terms of [the Government's] consent to be sued'... The appropriate inquiry, therefore, is whether Congress clearly and unequivocally departed from its usual practice in this area, and granted a right to trial by jury.") (quoting *United States v. Testan*, 424 U.S. 392, 399 (1976); *United States v. Mitchell*, 445 U.S. 535, 538 (1980)).

B. Summary Judgment on Patent Ineligibility

The district court did not err as a matter of law in denying Bhagat's motion to strike the PTO's motion for summary judgment or in granting the PTO's motion for summary judgment.

1. Denial of Bhagat's Motion to Strike

It was not an abuse of discretion for the district court to determine that the PTO's summary judgment motion was not premature. *See Harrods*, 302 F.3d at 244 ("We review for abuse of discretion the district court's refusal to allow [a party] the opportunity to engage in discovery prior to the entry of summary judgment.").

The Fourth Circuit makes clear that "[i]f a party believes that more discovery is necessary for it to demonstrate a genuine issue of material fact, the proper course is to file a Rule 56(f) affidavit" explaining that more time for discovery is needed for that party to oppose the motion for summary judgment. *Id.* While courts have, in some cases, found that summary judgment was premature without the opposing party filing a Rule 56(f) affidavit, in general, "the failure to file an affidavit under Rule 56(f) is itself sufficient grounds to reject a claim that the opportunity for discovery was inadequate." *Id.* (quoting *Evans v. Techs. Applications & Serv. Co.*, 80 F.3d 954, 961 (4th Cir. 1996) (internal quotations removed)). Here, Bhagat does not dispute that she failed to file a Rule 56(f) affidavit. Further, this is not a case where "the nonmoving party, through no fault of its own, has had little or no opportunity to conduct discovery," which can sometimes justify a finding that summary judgment was premature without a Rule 56(f) affidavit, because Bhagat has had ample time to complete discovery and, as previously discussed, chose to wait three months to begin pursuing discovery. *Id.* Thus, the district court did not abuse its discretion in denying to Bhagat's motion to strike

the PTO's motion for summary judgment as premature.

2. Grant of Summary Judgment

Further, the district court correctly granted the PTO's unopposed motion for summary judgment, since there were no disputed issues of material fact to contradict the finding that the Application claims were patent ineligible under Section 101 and that the pending claims were unpatentable under Section 103. Bhagat did not file an opposition to the PTO's summary judgment motion and instead relies on her briefing in support of her motion to strike to argue that she raised issues of disputed fact. Appellant's Br. 49–50. However, Bhagat does not identify a single issue of disputed fact in her motion to strike briefing; instead, she merely included the conclusory statement that "the record is rife with other facts [besides Dr. Harris's testimony that Bhagat moved to exclude] that are in serious dispute." Mem. in Supp. of Mot. to Strike at 2, *Bhagat v. USPTO* (No. 1:20-cv-01515), ECF 91. Thus, Bhagat has put forth nothing to contradict the PTO's account of the undisputed facts in its summary judgment motion. *See S.E.C. v. Farkas*, 557 F. App'x 204, 207 (4th Cir. 2014) (holding that the court is allowed to treat the movant's facts as undisputed when the nonmovant fails to dispute the movant's assertions of fact).

The district court therefore did not err in granting the PTO's motion for summary judgment that the Application claims are patent ineligible under Section 101, or in the alternative, that the pending claims are obvious under Section 103.

The district court correctly found that the Application claims were directed to a product of nature or abstract idea under *Alice* step one and that no additional claim elements transformed the ineligible subject matter into a patent-eligible invention. *Alice*, 573 U.S. at 217; *Mayo Collaborative Servs. v. Prometheus Lab'y, Inc.*, 566 U.S. 66, 71 (2012). Bhagat put forth no evidence to contradict the PTO's assertion that the claimed nutritional formulations were the same combination of nutrients found naturally in almonds; on appeal, her only contention is that the Application expressly disclaims almonds when it says, "wherein omega-6 fatty acid(s) and antioxidant(s) are not any single specific variety of a vegetable, a fruit, a nut, or a seed." Appellant's Br. at 54 (quoting Application claim 82). However, limiting the form of the servings of the nutritional formulations to require a mixture of fatty acids and antioxidants—rather than "any specific variety of a vegetable, a fruit, a nut, or a seed"—does not change the undisputed fact that the nutritional compositions Bhagat seeks to claim exist in nature. Bhagat also does not dispute that claim 112 is directed to the abstract idea of meal planning. Appellant's Br. 52–57. Thus, the district court did not err in finding that the Application claims were directed to a product of nature and an abstract idea.

Bhagat also fails to argue that the additional claim elements such as packaging, labeling, administering, preparing, and computer-automating are not conventional activities that are able to transform the Application into a patent-eligible invention. Instead, she simply asserts that the "claims as a whole are not well-understood" and relies

on the absence of a Section 102 rejection for lack of novelty for this proposition. Appellant's Br. 56–57. This is insufficient to preclude the district court from finding on summary judgment that the additional limitations were well understood and thus insufficient under *Alice* step two to turn the patent ineligible subject matter into a protectable invention. *See Genetic Techs. Ltd v. Merial L.L.C.*, 818 F.3d 1369, 1376 (Fed. Cir. 2016) ("[T]he inventive concept necessary at step two of the *Mayo/Alice* analysis cannot be furnished by the unpatentable law of nature (or natural phenomenon or abstract idea) itself."); *PersonalWeb Techs. LLC v. Google LLC*, 8 F. 4th 1310, 1318 (Fed Cir. 2021) ("[A] new abstract idea is still an abstract idea."). Thus, the district court correctly found that the Application claims were ineligible for patent protection under Section 101.

Finally, the district court's conclusion that the Application's pending claims should alternatively be rejected on Section 103 grounds was proper. Since Bhagat did not oppose the PTO's motion for summary judgment or contradict any of the PTO's undisputed facts, it was not erroneous for the district court to find that the prior art's disclosure of the nutritional formulations in the Application claims in overlapping ranges established a presumption of obviousness that Bhagat failed to overcome. The prior art discloses the same nutrients claimed in Bhagat's Application claims in overlapping dosages, and she fails to put forth facts that would establish teaching away or unexpected results. Bhagat provided no evidence in her motion to strike that the prior art taught away or led to unexpected results, and on appeal argues that the presence of some formulations in Morris in

different dosages of the nutrients taught away and relies on conclusory statements that the results were unexpected. Bhagat's belated arguments are insufficient to preclude summary judgment.

CONCLUSION

For the reasons stated above, we hold that the district court did not abuse its discretion in issuing any of the challenged orders, did not err in dismissing Bhagat's non-patent claims, and did not err in denying Bhagat's motion to strike the PTO's motion for summary judgment or in granting summary judgment in favor of the PTO.

AFFIRMED

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division
(July 22, 2021; Dkt. 25)

URVASHI BHAGAT,

Plaintiff

UNITED STATES PATENT AND TRADEMARK OFFICE, et al.,

Defendants

Civil Action No. 1:20-cv-1515

MEMORANDUM OPINION

THIS MATTER comes before the Court on Defendants' partial Motion to Dismiss Plaintiff's First Amended Complaint pursuant to Federal Rules of Procedure 12(b)(1) and 12(b)(6). The Court also considers Defendants' Motion to Strike Plaintiff's Jury Demand pursuant to Rule 39(a)(2).

In 2013, Plaintiff filed a patent application with the U.S. Patent and Trademark Office ("USPTO"). This application contained claims for nutritional formulations comprising omega-6 fatty acids and antioxidants. The USPTO examiner who reviewed Plaintiff's application withdrew claim 112 for lack of "unity of invention." The USPTO rejected Plaintiff's other pending claims for lack of written description, indefiniteness, improper dependency, and/or

obviousness. Plaintiff appealed the USPTO's rejections to the Patent Trial and Appeal Board, which affirmed all rejections except for the lack of written description. Plaintiff then filed the present case in this Court appealing the Board's decision. She amended the Complaint on April 19, 2021.

Defendants filed the present Motion to Dismiss on May 3, 2021. The Motion seeks dismissal of all Plaintiff's causes of action unrelated to the patentability of Plaintiff's application claims. Defendants identify several causes of action unrelated to Plaintiff's patent claims, including a takings claim under the Fifth Amendment, a general claim for damages due to the USPTO's allegedly bad faith delay of Plaintiff's patent issuance, a claim of tortious harassment, and a mandamus compelling the USPTO to issue Plaintiff's requested patent claims. Plaintiff demands a jury trial on all issues triable by a jury. Defendants filed a Motion to Strike such demand on May 3, 2021.

A district court must dismiss an action if the court has no subject matter jurisdiction over the claim. See Fed. R. Civ. P. 12(b)(1). The Court finds it lacks jurisdiction over the Amended Complaint's Fifth Amendment takings claim, general claim for money damages, and harassment claim.

Generally, agencies of the United States are shielded from liability under the doctrine of sovereign immunity unless Congress expressly waives such immunity. Congress has not waived its sovereign immunity for money damages in actions brought pursuant to 35 U. S.C. S 145. Any claims for money damages brought under this statute are dismissed for lack of subject matter jurisdiction.

The Tucker Act waives sovereign immunity with respect to non-tort monetary damage claims, such as violations of the Takings Clause of the Fifth Amendment, against the United States. But "a claim for just compensation under the takings clause must be brought to the Court of Federal Claims in the first instance." E .Enters. v. Apfel, 524 U.S. 498, 520 (1998). The U.S. Court of Federal Claims has exclusive jurisdiction over any such claims alleging damages greater than $10,000. See id.

In the present action, Plaintiff claims $500,000,000 in damages against the United States. Thus, the Court of Federal Claims has exclusive jurisdiction over this claim. Plaintiff's Fifth Amendment takings claim is dismissed for lack of subject matter jurisdiction.

Like the Tucker Act, the Federal Tort Claims Act ("FTCA") waives the Government's sovereign immunity for any "injury or loss caused by the negligent or wrongful act of a Government employee acting within the scope of his or her employment." Medina v. United States, 259 F.3d 220, 223 (4th Cir. 2001). This waiver includes actions for tortious harassment, so long as they are otherwise proper before the Court. But for an FTCA claim to be properly before the Court, a plaintiff must first present an administrative claim to the agency allegedly responsible for the plaintiff's injury. See 28 U.S. C. S 2675(a).

In this case, the relevant agency would be the USPTO because the Amended Complaint alleges the USPTO is responsible for harassing Plaintiff. But the Amended Complaint does not indicate that Plaintiff first filed a claim with the USPTO regarding said

harassment. Without first filing this claim with the USPTO, this Court has no authority to review the harassment claim. It is dismissed for lack of subject matter jurisdiction.

A complaint should be dismissed for failure to state a claim pursuant to Rule 12(b)(6) "if after accepting all well-pleaded allegations in the plaintiff's complaint as true... it appears certain that the plaintiff cannot prove any set of facts in support of his claim entitling him to relief." Edwards v. City of Goldsboro, 178 F.3d 231, 244 (4th Cir. 1999). A plaintiff must allege "a plausible claim for relief," instead of merely stating facts that leave open "the possibility that a plaintiff might later establish some set of undisclosed facts to support recovery." McCleary-Evans v. Md. Dep't of Transp., State Highway Admin., 780 F.3d 582, 587 (4th Cir. 2015) (emphases in original).

Although a court considering a motion to dismiss must accept all well-pleaded factual allegations as true, this deference does not extend to legal conclusions. Neither "naked assertions devoid of further factual enhancement," nor "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements" suffice. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

Courts are instructed to construe pro se pleadings liberally. "[W]hen reviewing a pro se complaint, a court must carefully examine the plaintiff's allegations, no matter how inartfully pleaded to determine whether they could provide a basis for relief." Johnson v. Lyddane, 368 F. Supp . 2d 529, 531 (E.D. Va. 2005) (citing Gordon v. Leeke, 574 F. 2d 1147, 1151 (4th Cir. 1977)).

The Amended Complaint includes no facts supporting the conclusion that the USPTO violated Plaintiff' s constitutional rights, that the USPTO made false statements, and that Plaintiff is plausibly entitled to mandamus relief.

To establish she is eligible for mandamus relief, a plaintiff must plead (1) she has a clear right to the relief requested and (2) no other relief is available. See Heckler v. Ringer, 466 U.S. 603, 616 (1984). The Amended Complaint does not plausibly allege either. Plaintiff has not established that the USPTO owes her a clear duty to issue her a patent. And there is at least one other form of relief, i.e., 35 U. S.C. § 145, which Plaintiff has also asserted in her Amended Complaint. Plaintiff' s petition for mandamus is thus dismissed for failure to state a claim.

The Amended Complaint also fails to allege plausible misconduct or false statements by the USPTO. Though Plaintiff alleges the USPTO erred in the adjudication in her patent application, she provides no factual support for the allegation that the USPTO made false statements or acted with misconduct. The conclusion that the USPTO acted with "misconduct" is insufficient without providing any factual support of alleged misconduct. And the conclusion that "the Chief Judge also made false statements" is insufficient without any plausible explanation as to what statements were objectively false. These claims must be dismissed for failure to state a claim.

The Amended Complaint similarly alleges the USPTO violated Plaintiff's constitutional rights, but Plaintiff fails to set forth what action the USPTO took that violated her rights, or even which constitutional

right was violated. This cause of action also must be dismissed for failure to state a claim.

Finally, Defendants ask the Court to strike Plaintiff's request for a jury trial. "It has long been settled that the Seventh Amendment right to trial by jury does not apply in actions against the Federal Government." Lehman v. Nakshian, 453 U.S. 156, 160 (1981). When Congress waives its sovereign immunity—as it has done with respect to patent appeals pursuant to 35 U.S.C. § 145—a plaintiff has a right to a jury trial only when Congress "unequivocally expresse[s]" such right in the authorizing statute. Id. Here, 35 U.S.C. S 145 provides no such unequivocal waiver. Thus, Plaintiff has no right to a jury trial on her sole remaining claim.

For the foregoing reasons, all causes of action in the Amended Complaint—except that which was brought pursuant to 35 U.S.C. § 145—must be dismissed pursuant to Federal Rules of Civil Procedure 12(b)(1) and (6). Plaintiff's request for a jury trial is struck. An appropriate order shall issue.

CLAUDE M. HILTON
UNITED STATES DISTRICT JUDGE

Alexandria, Virginia
July 22, 2021

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division
(July 22, 2021; Dkt. 26)

URVASHI BHAGAT,

Plaintiff

UNITED STATES PATENT AND TRADEMARK OFFICE, et al.,

Defendants

Civil Action No. 1:20-cv-1515

ORDER

For the reasons stated in the accompanying Memorandum Opinion, it is hereby

ORDERED that Defendants' Partial Motion to Dismiss Plaintiff's First Amended Complaint is GRANTED. It is further

ORDERED that Defendants' Motion to Strike Plaintiff' s Jury Demand is GRANTED. A scheduling order shall issue.

CLAUDE M. HILTON
UNITED STATES DISTRICT JUDGE

Alexandria, Virginia
July 22, 2021

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division
(December 16, 2022; Dkt. 67)

URVASHI BHAGAT,

Plaintiff

UNITED STATES PATENT AND TRADEMARK OFFICE, et al.,

Defendants

Civil Action No. 1:20-cv-1515

ORDER

This matter is before the Court on Plaintiff Urvashi Bhagat's continued ex parte email communications with the Court. By Plaintiff's own admission, she has been constantly emailing and calling the Court requesting various forms of relief despite being informed by the Court, on more than one occasion, that written motions are the only appropriate form by which to request relief from the Court. [Dkt. No. 64-1]. As the Court has previously stated, email is an inappropriate way to request relief. Ex parte communications, or communicating with the Court without including the other party on any communication with the Court, are even more inappropriate.

This Court granted Plaintiff's motion for Pro Se E-Noticing [Dkt. No. 7], but that does not allow Plaintiff to file documents or requests for relief electronically. The proper procedure for requesting relief from the Court is filing a paper copy of any motion through the Clerk's Office that includes the relief requested and a legal basis for granting such relief. Plaintiff is directed to obtain a copy of, and review, the United States District Court for the Eastern District of Virginia Pro Se Reference Handbook from the Clerk's Office concerning the rules applicable to and the appropriate manner by which to proceed in this civil action. The Court will respond to no further email or phone communications.

ENTERED this 16th day of December 2022.

Ivan D. Davis
United States Magistrate Judge

Alexandria, Virginia

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division
(December 30, 2022; Dkt. 75)

URVASHI BHAGAT,

Plaintiff

UNITED STATES PATENT AND TRADEMARK OFFICE, et al.,

Defendants

Civil Action No. 1:20-cv-1515

ORDER

This matter is before the Court on Plaintiff's Objections to the Entry of the Order Dated December 16, 2022 ("Motion") [Dkt. No. 70]. The Court interprets the Motion as a Motion to Vacate the December 16, 2022 Order. This matter can be resolved without oral argument, as such argument would not aid the decisional process. Upon consideration of the Motion and for lack of good cause shown, it is hereby

ORDERED that the Motion is DENIED. To clarify the Court's December 16, 2022 order, Plaintiff should never contact chambers regarding any substantive issues concerning the case unless authorized by the Court in advance. However, Plaintiff may contact the Clerk's Office for any administrative or logistical questions. In addition, the Court finds no

inconsistencies between the United States District Court for the Eastern District of Virginia Pro Se Reference Handbook ("Handbook") and Federal Rule of Civil Procedure 6(b)(1)(A). The Court's ability to sua sponte grant an extension of time "with or without motion or notice" as noted in the rule, is different from the Handbook's requirement to file a motion if a litigant wants "to ask the Court to order something." Furthermore, it is not "routine practice" for parties to directly contact chambers to request a conference call without first meeting and conferring with one another in good faith to narrow any areas of disagreement or to jointly request relief, even in urgent matters. Generally, the Court does not consider extensions of time urgent, and such extensions/continuances are disfavored by the Court.

ENTERED this 30th day of December 2022.

Ivan D. Davis
United States Magistrate Judge

Alexandria, Virginia

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division
(January 10, 2023; Dkt. 77)

URVASHI BHAGAT,

Plaintiff

UNITED STATES PATENT AND TRADEMARK OFFICE, et al.,

Defendants

Civil Action No. 1:20-cv-1515

ORDER

This matter is before the Court on Plaintiff's Motion for Extension of Time for Expert Rebuttal Reports & Further Enlargement of Discovery and a Continuance of the Final Pre-Trial Conference ("Motion") [Dkt. No. 62]. This matter can be resolved without oral argument, as such argument would not aid the decisional process. Upon consideration of the Motion, it is hereby

ORDERED that the Motion is **GRANTED in part and DENIED in part.** The Court extends the due date for Plaintiff's rebuttal disclosures to December 9, 2022. The motion is denied in all other respects.

The Motion is denied in part for the following reasons. First, Plaintiff fails to show good cause, based

upon excusable, neglect for any extension of the current discovery cutoff and Final Pretrial Conference date. Regarding the timeliness of her motion, Plaintiff argues that she contacted Ms. Jessica Leonardo, law clerk to the Honorable U.S. District Judge Claude M. Hilton, on numerous occasions, by phone and email, prior to the expiration of the discovery cutoff date, in an attempt to request a discovery enlargement. However, Ms. Leonardo was no longer a law clerk for Judge Hilton on the dates the Plaintiff attempted to contact her. In addition, the Court has repeatedly notified Plaintiff that the proper way to request relief is through a written motion. While "the court *may*, for good cause, extend the time" "with or without motion or notice if the court acts, or if a request is made, before the original time or its extension expires," the Court is not *required* to accept oral motions. Fed. R. Civ. Pro. 6(b)(1)(B). Once again, the Court reminds Plaintiff that a written motion is the proper way to request relief from this Court. Therefore, the Court does not excuse Plaintiff's failure to file her written motion until after the discovery cutoff.

Nevertheless, even if the Court deemed Plaintiff's motion timely filed, the Court finds that Plaintiff has failed to show good cause for her requested extensions. The District Judge's Initial Scheduling order noted that the parties could begin discovery as of the date of the order, August 11, 2022. However, Plaintiff waited until November 1, 2022 to participate in the discovery process, eight days before the close of discovery. Plaintiff states that she waited to serve discovery requests until after the Supreme Court ruled on the petition for writ of mandamus. Dkt. No. 64. Waiting to serve discovery requests until after a Supreme

Court ruling on her writ was a legal strategy, the consequences of which Plaintiff must face. The Court cannot allow the Plaintiff to benefit from her failed legal strategy. In addition, since any ruling from the Supreme Court could have only affected discovery regarding the appealed dismissed claims and not the remaining claims in the case, failing to proceed with discovery concerning those remaining claims, prior to any Supreme Court ruling, constituted a lack of due diligence by the Plaintiff in participating in the discovery process. While pro se litigants are afforded "some leeway" in cases, the Court finds that waiting until November 1, 2022 to participate in discovery is far more than "some leeway." Therefore, Plaintiff fails to meet her burden under the good cause standard.

Plaintiff also raises two other reasons in support of granting her motion; the Court will address each in turn. First, Plaintiff states that Defendants have more manpower and resources than Plaintiff so she should be granted more time. However, parties in this District routinely have disparity in manpower and resources. That disparity alone does not amount to good cause for an extension of deadlines. Second, Plaintiff also raises concerns about her personal workload on the case, stating that she was unable to take depositions of the Defendants because she did not have the time. She further states that she has not reviewed Defendants' responses to her discovery requests because she was busy working on the expert rebuttal disclosures. Plaintiff's inability to manage her time throughout the litigation also constitutes a lack of due diligence and, therefore, does not amount to good cause for an extension of previously scheduled court deadlines. Accordingly, this Court does not find

good cause for the discovery enlargement or continuance of the final pretrial conference.

On January 9, 2023, the Court received an email from Plaintiff inquiring about the status of the Motion and informed the Court of her intent to appeal the order if the Court denied the Motion. The Court reminds Plaintiff that it is inappropriate to address the Court on a pending motion, and that it is also inappropriate for Plaintiff to notify the Court of her intent to appeal a pending motion if it is denied. The Court also reminds Plaintiff, once again, that a written motion is the proper way to request relief from this Court.

ENTERED this 10th day of January 2023.

Ivan D. Davis
United States Magistrate Judge

Alexandria, Virginia

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division
(January 17, 2023; Dkt. 83)

URVASHI BHAGAT,

Plaintiff

UNITED STATES PATENT AND TRADEMARK OFFICE, et al.,

Defendants

Civil Action No. 1:20-cv-1515

ORDER

THIS MATTER comes before the Court on Plaintiff's Motion to Disqualify Dr. William S. Harris as Expert Witness for Defendants.

Plaintiff argues that Dr. Harris should be excluded because he is bias and Plaintiff disagrees with his opinions. Plaintiff's objections go to the weight of the expert' s testimony, not admissibility. It is hereby

ORDERED that Plaintiff' s Motion to Disqualify Dr. Harris as Expert Witness for Defendants is DENIED.

CLAUDE M. HILTON
UNITED STATES DISTRICT JUDGE

Alexandria, Virginia
January 17, 2023

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division
(March 30, 2023; Dkt. 124)

URVASHI BHAGAT,

Plaintiff

UNITED STATES PATENT AND TRADEMARK OFFICE, et al.,

Defendants

Civil Action No. 1:20-cv-1515

MEMORANDUM OPINION

THIS MATTER comes before the Court on Defendant' s Motion for Summary Judgment pursuant to Federal Rule of Civil Procedure 56 and Plaintiff' s Motion to Strike Defendant's Motion for Summary Judgement.

The Court first addresses Plaintiff's Motion to Strike Defendant' s Motion for Summary Judgement or Stay Briefing of the Motion Pending the Outcome of Plaintiff's Appeal. The Motion for Summary Judgement is not premature. Plaintiff has had over four months to conduct discovery and has used that time to conduct her discovery. The Motion to Strike should be denied.

The Fourth Circuit's February 23, 2023 Order that consolidated Plaintiff's appeals also dismissed as moot

Plaintiff's Motion for a Stay of the District Court proceedings. This Court finds Plaintiff has failed to carry the burden to support a stay pending interlocutory appeal of discovery matters.

Plaintiff is the inventor of the United States Patent Application No. 13/877,847 (the "Application"). The Application describes nutritional formulations as supplements, meal components, or meals, that may be administered in any orally acceptable form, including, capsules, tablets, liquid formulations, or whole foods. This includes specifying that the nutritional formulation may comprise one or more nuts, including almonds, and that nuts are a source of omega-6 fatty acids, antioxidants, and polyphenols. The Application discusses administering the formulations at various frequencies including one to three times a day.

The Application also includes that different formulations may be packaged together or in single units and in different types of packaging including in a gelatinous case, a vial, a bottle, a pouch or a foil, or plastic or card-board box. It further states that formulations may be marked to indicate the intended consumer, the frequency of consumption, the suitability for consumption according to a general diet plan, or the maximum amounts for average daily consumption.

There are "method of using" claims included in the Application. This includes Claim 88 which recites steps to administer a dosage to an individual selected from a diet cohort that is based on gender, age, genetic profile, family history, climactic temperature, or medical condition. Claims 97 and 116 relate to methods of treatment of either unspecified medical conditions or diseases, or any of a long list of widely

divergent conditions and diseases, through administering nutritional formulations. One of the examples included in the Application is a subject given a composition that included a combination of vegetable oils, nuts, and seeds. Claim 99 relates to methods of preparing a product comprising nutritional formulations, including the steps of determining the individual' s diet cohort and selecting and preparing at least one formulation that provides 1 to 40 g of omega-6 fatty acids, 25 mg to 10 g of antioxidants, and greater than 5 mg of polyphenols.

However, none of the Application' s method claims include tailoring the nutrient dosages in the product to the diet cohort or restricting the total daily intake of any of the claimed nutrients.

Claim 112 deals with a computer system to implement the method of Claim 99 and recites a system that outputs a nutritional plan for an individual based on their dietary preferences and dietary guidelines.

The United States Patent and Trademark' s Patent Trial and Appeal Board (the "Board") affirmed the rejection of the Plaintiff's Application claims because they were obvious in light of numerous past expert studies and disclosures. In particular, the Board used a work by inventor Claudia R. Morris, US Published Patent Application Number 2008/0213239 Al (hereinafter "Morris"), which discloses preparing and administering dietary formulations comprising omega-6 fatty acids and Vitamin E to children and adults for treating various conditions such as cardiovascular disease. The formulations may be in the form of tablets, capsules, food bars, or drinks. Morris discloses that the formulations comprise

omega-6 fatty acids, such as linoleic acid, in dosages and amounts overlapping the dosages in Plaintiff's claims. Morris shows that the formulations comprise from about 50 mg to about 500 mg omega-6 fatty acids that may be administered once, twice, or three times daily, which would equal a dosage ranging from 50 mg to 1,500 mg of omega-6 fatty acids a day. There is further overlap where Morris shows that the formulation comprises Vitamin E in amounts and dosages that overlap the Plaintiff's claimed dosages.

The Board further found that Morris discloses packaged formulations comprising omega-6 fatty acids, Vitamin E, and polyphenols. Morris also discloses dosages of omega-6 and Vitamin E overlapping the claimed ranges. The Board determined the claimed dosages were obvious due to Morris' s disclosure that dosages are a result-effective variable and may be optimized for an individual. Morris also discusses preparing formulations based on an individual' s age, weight, genetic makeup, etc., which equates to Plaintiff's Claim 99 limitation of preparing a formulation based on the diet cohort of an individual.

The only difference the Board found between Morris and the Plaintiff's claimed formulation was an explicit disclosure of using nutrients from different sources. However, this would have been obvious in light of another expert's teachings of oil blends from different sources.

Plaintiff brought this suit pursuant to 35 U.S.C. § 145 the Board affirmed the rejection of all pending claims of Plaintiff's Application.

A Section 145 appeal is a hybrid action because it is partially an appeal from an administrative body and partially a new evidentiary proceeding. See Hyatt v. Kappos, 625 F.3d 1320, 1322 (Fed. Cir. 2010); Halozyme, Inc. v. Iancu, 320 F. supp. 3d 788, 801-02 (E.D. Va. 2018) (Hilton, J.). New evidence may be presented but the Board's decision remains at the center of the case. Hyatt, 625 F.3d at 1322. When a party presents new evidence not previously before the Board, the court makes a de novo finding on any disputed questions of fact. Kappos v. Hyatt, 566 U.S. 431, 433- 434 (2012). The issue of patent eligibility is a question of law for the court.

Under Federal Rule of Civil Procedure 56, a court should grant summary judgment if the pleadings and evidence show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); see Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). In reviewing a motion for summary judgment, the court views the facts in the light most favorable to the non-moving party. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). Once a motion for summary judgment is properly made, the opposing party has the burden to show that a genuine dispute of material fact exists. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986).

The Court finds there are no issues of material fact as to any of Plaintiff's claims and their patent ineligibility under 35 U.S.C. §§ 101 and 103.

The two-step framework for determining whether claims that are within a statutory category nevertheless fall within a patent-ineligible exception, is set out by the Supreme Court in Alice corp. Pty. Ltd.

v. CLS Bank Int'l, 573 U.S. 208 (2014). Step one is "whether the claims at issue are directed at one of [the] patent-ineligible concepts." Id. at 217. The patent-ineligible concepts include laws of nature, natural phenomena, and abstract ideas. If claims are directed at one of the patent-ineligible concepts, then the court moves to step two and considers the elements of each claim "both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." Id. at 217-218.

Each of Plaintiff's claims of the Application at issue deal with products of nature or abstract ideas that are patent ineligible under 35 U.S.C. § 101.

Plaintiff's claims 82-89, 91-104, 107-110, and 113-120 of the Application contain a recitation of the combination of nutrients naturally present in almonds and thus are a natural product. Further, the claims do not have any limitations that transform the natural product into patent-eligible subject matter.

Independent claims 82, 99, 115, and 116 recite nutritional formulations with a combination of nutrients in various specified dosages. These claimed nutrients are naturally present in almonds, making the claims about a natural product. Since almonds contain all of the claimed nutrients, the claims do not recite a product with any markedly different characteristics from those found in nature.

The court begins with step one to determine if the claims fit into a patent-ineligible statutory category. Independent claim 82 is a product claim, and its patentability depends on the product. The claim' s

recitation of the nutrients coming from an intermixture process using different sources does not change the conclusion that it is a natural product. The patentability of a product claim depends on the product and not the process of making it.

Independent claim 82's dependent claims 95, 103, 109, and 110 clarify that the independent claim's formulation encompass nuts. Dependent claims 88, 91, 96-98, 102, and 104 do not make any attempt to further limit the nutrient composition. Dependent claims 83, 84, 100, and 115-118 merely recite the same nutrients which almonds comprise. Also, almonds contain the dosages of omega-6 fatty acids recited in claims 92, 107, 113, and 119, and the polyphenol dosage recited in claim 120. Almonds further comprise phytosterols as required by claim 85, in the dosages recited in claims 86, 93, 108, and 114.

Claim 94' s requirement that one formulation provide omega-6 fatty acids in a dosage less than 1 g, but that a plurality collectively provide 1 to 40 g of omega-6 merely encompasses a product of 100 g of almonds broken into 5 g increments. Almonds also contain the phytochemicals, lipids, antioxidants, vitamins, minerals, and fiber recited in claims 87 and 101. Finally, claim 89 encompasses a mixture of one or more food items, which includes a mixture of 100 g of almonds with other nuts.

Having determined that the product and method claims of the Application are about a natural product under the first step of the Alice inquiry, the court now moves to step 2 to determine if the additional claim elements transform the natural product into a patent-eligible application. Transformation of a natural product into eligible subject matter requires the

additional features be more than "well-known understood, routine, conventional activit[ies] . " See Alice at 225.

Plaintiff's independent product claim 82, simply recites well-known routing and conventional activity of packaging and labeling the formulations. This includes basic packaging such as in "a vial, a bottle, a pouch or a foil, or plastic and/or cardboard box, and the like." This type of basic, common-place packaging is a conventional activity.

Claim 82' s dependent claims, 91 and 95, fail to add any transformative claim limitations. Claim 91 limits the formulations into particular forms like powder. Unfortunately, it is well known that nuts can be crushed into a powder. Claim 95 recites that the formulation is in a "kit" which is nothing more than conventional packaging of the formulation.

Claims 83-87, 89, 92-94, 113-114, 117, and 119-120 are also dependent claims from claim 82, but do not recite any limitations beyond the natural product itself or additional natural products.

Independent claim 115 is also directed to just the natural product. Therefore, all of the product claims of the Application are patent ineligible.

Claims 88, 96-98, and 116 recite methods of administering the natural product. Beyond the natural product itself, the only limitation recited in claim 88 is the step of administering to an individual that belongs to a specified diet cohort. Administering, which includes eating or feeding, almonds to an individual is a conventional activity. The "diet cohort" limitation just identifies the intended recipient of the natural product and does so in a generic manner that

all humans would qualify. Claims 96-98 and 116 are methods of treating either unspecified medical conditions or a long list of widely divergent conditions by administering the natural product and administering is still a routine and conventional activity.

Independent claim 99 and its dependent claims recite methods of preparing nutritional formulations for an individual which include "determining," "selecting," and "preparing" steps. Each step, however, is insufficient to transform the naturally occurring nutritional formulation, almonds, into patent -eligible subject matter. First, the "determining" step simply groups the individuals into diet cohorts, which the Application explains broadly includes a grouping based on food preference, dietary habits, age, or gender. Grouping individuals on the basis of these generic and broad categories is well-known and conventional. Second, the "selecting and preparing" step simply links the choice of nutritional formulation to the grouping. The additional limitations of claim 99 are therefore nothing more than post-solution activities related to preparing a natural product for consumption that do not transform the claims from being directed to the ineligible natural product.

Dependent claims 102, 104, 109, and 110 recite more limitations on the method of preparing but are not directed to anything more than the natural product itself.

Claim 112 deals with a computer system that implements the method of preparing the product from claim 99. It takes dietary preferences and guidelines to generate a nutrition program. This is a type of meal

planning that is a method for organizing human activity and thus an abstract idea. Further, the additional elements given in claim 112 only add conventional computer components and are not sufficient to transform the claimed computer system into a patent-eligible invention.

Further showing the Application's patent-ineligibility, Plaintiff's claims of the Application are obvious under 35 U.S.C. § 103.

A claim is unpatentable under § 103 if the differences between the claims and the prior art would have been obvious to a person of ordinary skill in the art at the time of the invention. A presumption of obviousness exists if the claims recite a range that overlap with what is disclosed in the prior art. Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1311 (Fed. Cir. 2006). Here, the prior art teaches all the claimed nutrients in dosages overlapping the claimed ranges, thereby establishing such a presumption.

As the Board correctly found, claims 82-89, 91-104, 107-110, and 113-120 of the Application would have been obvious given the teachings of Morris and inventors Joshua C. Anthony et al., US Published Patent Application Number 2007/0166411 Al (hereinafter "Anthony"). The Board treated claim 82 as representative, finding Plaintiff did not separately argue the patentability of any dependent claims as required under 37 C.F.R. § 41.37(c)(1)(iv). As the party that "seeks to change an administrative result," Plaintiff bears the "burden" of showing error in that determination. Cal. Rsch. Corp. v. Ladd, 356 F.2d 813, 819 (D.C. Cir. 1966).

The Board further found that Morris teaches preparing and administering a packaged dietary formulation comprising omega-6 fatty acids, Vitamin E, and polyphenols. It also found that Morris teaches dosages of omega-6 fatty acids and Vitamin E overlapping the claimed range.

As Defendants' expert witness Dr. William S. Harris explained, in addition to being obvious over Morris and Anthony, the benefits of consuming the claimed nutrients were well-known in the art as of 2010. This is reflected in an additional three combinations of references that also render claims 82-89, 91-104, 107- 110, and 113-120 obvious. These additional reference combinations disclose the claimed omega-6 fatty acid, antioxidant, and polyphenol dosages that have been the focus of Plaintiff's arguments throughout this proceeding. Plaintiff has not argued with particularity why this prior art does not disclose any additional limitations in the dependent claims.

Plaintiff asserts that Morris teaches away because its examples contain no or low amounts of omega-6 fatty acids and its antioxidant range. However, Plaintiff fails to establish unexpected results to rebut the presumption of obviousness based on the overlapping ranges of the prior art and Plaintiff has not shown any additional teaching away to rebut the presumption of obviousness.

Lastly, Plaintiff attempts to argue the prior art is not relevant because it does not address the problem solved by her Application. However, the prior art is from the same field of endeavor in nutritional formulations as the Application and therefore is relevant art in this case.

For the foregoing reasons, Defendant' s Motion for Summary Judgment should be granted.

An appropriate Order shall issue.

CLAUDE M. HILTON
UNITED STATES DISTRICT JUDGE

Alexandria, Virginia
March 30, 2023

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division
(March 30, 2023; Dkt. 125)

URVASHI BHAGAT,

Plaintiff

UNITED STATES PATENT AND TRADEMARK OFFICE, et al.,

Defendants

Civil Action No. 1:20-cv-1515

ORDER

In accordance with the accompanying Memorandum Opinion, it is hereby

ORDERED that Defendant' s Motion for Summary Judgment is GRANTED and Plaintiff' s Motion Strike Motion for Summary Judgement or Stay Proceedings is DENIED. This case is hereby DISMISSED.

CLAUDE M. HILTON
UNITED STATES DISTRICT JUDGE

Alexandria, Virginia
March 30, 2023

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division
(March 31, 2023; Dkt. 126)

URVASHI BHAGAT,

Plaintiff

UNITED STATES PATENT AND TRADEMARK OFFICE, et al.,

Defendants

Civil Action No. 1:20-cv-1515

ORDER

THIS MATTER comes before the Court on Plaintiff' s Motion for Leave to File Second Amended Complaint. Summary judgment has been granted for Defendant and this case was dismissed. It is hereby

ORDERED that Plaintiff's Motion for Leave to File Second Amended Complaint is DENIED.

CLAUDE M. HILTON
UNITED STATES DISTRICT JUDGE

Alexandria, Virginia
March 31, 2023

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

URVASHI BHAGAT,
Plaintiff-Appellant

v.

UNITED STATES PATENT AND TRADEMARK OFFICE, KATHERINE K. VIDAL, IN HER OFFICIAL CAPACITY AS UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE, UNITED STATES,
Defendants-Appellees

2023-1545

Appeal from the United States District Court for the Eastern District of Virginia in No. 1:20-cv-01515-CMHIDD, Senior Judge Claude M. Hilton.

ON PETITION FOR PANEL REHEARING AND REHEARING BANC

Before MOORE, *Chief Judge*, LOURIE, LEVENGER[1] DYK, PROST, REYNA, TARANTO, CHEN, HUGHES, STOLL, CUNNINGHAM, and STARK, *Circuit Judges*.[2]

PER CURIAM.

ORDER

On July 19, 2024, Urvashi Bhagat filed a combined petition for panel rehearing and rehearing en banc [ECF No. 63]. The petition was referred to the panel that heard the appeal, and thereafter the petition was referred to the circuit judges who are in regular active service.

Upon consideration thereof,
IT IS ORDERED THAT:
The petition for panel rehearing is denied.
The petition for rehearing en banc is denied.
The mandate of the court will issue August 28, 2024.

FOR THE COURT
Jarret B. Perlow
Clerk of Court

August 21, 2024
Date

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[1] Circuit Judge Clevenger participated only in the decision on the petition for panel rehearing.
[2] Circuit Judge Newman did not participate.

UNITED STATES PATENT AND TRADEMARK OFFICE

Application 13/877,847
Filing Date April 4, 2013
First Named Inventor Urvashi Bhagat
Confirmation Number 4620
Examiner Nina Bhat
Technology Center 3649

OFFICE COMMUNICATION CONCERNING THIS APPLICATION OR PROCEEDING
(February 15, 2018)
(Excerpts)

...

5. With respect to the 101 rejection over claims 82-96, 113 and 114 applicant's amendments to the claims obviates this rejection. Accordingly the 101 rejection made in the Office Action of July 11, 2017 is withdrawn.

...

16. ... the Examiner has written two allowable claims for applicant's review:

115. (New) 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.

116.(New) A method for treating medical conditions or diseases selected from the group consisting of menopause, aging, allergy, musculoskeletal disorders, vascular diseases, hypercholesterolemia, mood swing, reduced cognitive function, cancer, neural disorders, mental disorders, renal diseases, endocrine disorders, thyroid disturbances, weight gain, obesity, diabetes, digestive system disorders, reproductive disorders, infant abnormalities, pulmonary disorders, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, autoimmune diseases, infectious diseases, and inflammatory diseases by administering to a human subject the nutritional composition in an amount sufficient to treat the medical condition or disease wherein the nutritional composition comprises:

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), dihomo-gamma-linolenic (C20:3), and arachidonic (C20:4);

b) 25 mg-10 of an antioxidant selected from the group consisting of selected from the group 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.

Case No. 2023-1545

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

URVASHI BHAGAT,
Plaintiff-Appellant

v.

THE UNITED STATES PATENT AND TRADEMARK OFFICE, KATHERINE K. VIDAL, in her official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, UNITED STATES[4],
Defendants-Appellees.

On Appeal from The United States District Court For the Eastern District of Virginia, Alexandria Division, No. 1:20-cv-1515-CMH-IDD, Senior Judge Claude M. Hilton.

CORRECTED OPENING BRIEF OF THE APPELLANT

Urvashi Bhagat
PO Box 1000
Palo Alto, CA 94302
(650) 785-2516
bhagatu@asha-nutrition.com
Pro se Appellant ***Dated: December 17, 2023***

[4] Amended caption per order dated December 1, 2023, ECF No. 33.

INDEPENDENT PATENT CLAIMS AT ISSUE

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.

96. The method according to claim 97, wherein the dosage is administered to aid acid-base balance in the individual.

97. A method of prophylaxis and/or treatment of a medical condition or disease in the individual, the method comprising:
administering a dosage of the product according to claim 82 to the individual.

98. The method according to claim 97, wherein the medical condition or disease is selected from the group consisting of menopause, aging, allergy, musculoskeletal disorders, vascular diseases, hypercholesterolemia, mood swing, reduced cognitive function, cancer, neural disorders, mental disorders, renal diseases, endocrine disorders, thyroid disturbances, weight gain, obesity, diabetes,

digestive system disorders, reproductive disorders, infant abnormalities, pulmonary disorders, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, autoimmune diseases, infectious diseases, and inflammatory diseases

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.

112. A computer system configured to computationally implement a method according to claim 99, comprising:

(a) a computing device having a memory;

(b) an input device for entering information regarding the individual's dietary preferences into the memory;

(c) a database in the memory for storing the information;

(d) a first program module, for execution in the computing device, for determining a dietary cohort of the individual corresponding to the individual's dietary preferences, wherein the program operates in response to remote user inputs of dietary cohorts and/or preferences; wherein the dietary cohort of the individual is

(i) predetermined and entered directly in the computing device; and/or

(ii) determined either manually or computationally in response to remote user inputs of dietary preferences via a web connection; and/or

(iii) selected from predominantly vegetable-based, seafood based and meat based;

(e) a nutrient database for storing dietary guidelines relative to dietary cohorts of an individual; wherein optionally the nutrient database comprises suitable ranges for average daily dietary consumption of nutrients corresponding to each dietary cohort, and/or suitable ranges for daily dietary consumption of carbohydrates, protein, vitamins, minerals and phytochemicals;

(f) a knowledge database having rules for manipulating the information in the database to provide a recommended future nutrition program for the individual, the nutrition program comprising one or more of nutrients selected from antioxidants, phytochemicals, lipids, vitamins and minerals in amounts that provide a beneficial effect to the individual, wherein a suitable daily dosage of omega-

6 fatty acids and antioxidants including polyphenols is included in the program;

(g) a second program module, for execution in the computing device, for applying the rules in the knowledge database to the information in the database and to the guidelines in the nutrient database and for generating a nutrition program for the individual in a result database; and

(h) means for outputting the contents of the result database, under the direction of the second program module,

wherein the nutrition program comprises a listing of formulations, optionally comprising food items, wherein from 1 to 40g of omega-6 fatty acids and from 25mg to 10g of antioxidants comprising at least 5mg of one or more polyphenols are included in the program for daily consumption by the individual.

115. A nutritional formulation comprising a mixture of:

(a) from 1 to 40 g dosage of omega-6 fatty acid(s) selected from the group consisting of linoleic (C18:2), conjugated-linoleic (C18:2), gamma-linolenic (C18:3), eicosadienoic (C20:2), di-homo-gamma-linolenic (C20:3), and arachidonic (C20:4); and

(b) from 25 to 10 g dosage of antioxidant(s) selected from the group consisting of ascorbic acid (vitamin C), folic acid (folate), selenium, copper, zinc, superoxide dismutase (SOD), catalase, glutathione peroxidase (GSHpx), coenzyme Q10 (CoQ10), glutathione, vitamin A, vitamin E, and vitamin D; wherein

(c) the dosage of antioxidants includes at least 5 mg of phytochemical(s) selected from the group consisting of monophenols, polyphenols,

phenolic acids, hydroxycinnamic acids, tyrosols, carotenoids, monoterpenes, saponins, phytosterols, triterpenoids, betalains, organosulfides, indoles, glucosinolates, and sulfur compounds;

wherein the omega-6 fatty acid(s) and antioxidant(s) is not any single specific variety of a vegetable, a fruit, a nut, or a seed.

116. A method for treating medical conditions or diseases selected from the group consisting of menopause, aging, allergy, musculoskeletal disorders, vascular diseases, hypercholesterolemia, mood swing, reduced cognitive function, cancer, neural disorders, mental disorders, renal diseases, endocrine disorders, thyroid disturbances, weight gain, obesity, diabetes, digestive system disorders, reproductive disorders, infant abnormalities, pulmonary disorders, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, autoimmune diseases, infectious diseases, and inflammatory diseases, the method comprising:

administering to a subject the nutritional formulation in a dosage sufficient to treat the medical condition or disease wherein the nutritional formulation comprises:

(a) from 1 to 40 g dosage of omega-6 fatty acid(s) selected from the group consisting of linoleic (C18:2), conjugated-linoleic (C18:2), gamma-linolenic (C18:3), eicosadienoic (C20:2), di-homo-gamma-linolenic (C20:3), and arachidonic (C20:4); and

(b) from 25 to 10g dosage of antioxidant(s) selected from the group consisting of ascorbic acid (vitamin C), folic acid (folate), selenium, copper, zinc, superoxide dismutase (SOD), catalase, glutathione peroxidase (GSHpx), coenzyme Q10 (CoQ10),

glutathione, vitamin A, vitamin E, and vitamin D; wherein

(c) the dosage of antioxidants includes at least 5 mg of phytochemical(s) selected from the group consisting of monophenols, polyphenols, phenolic acids, hydroxycinnamic acids, tyrosols, carotenoids, monoterpenes, saponins, phytosterols, triterpenoids, betalains, organosulfides, indoles, glucosinolates, and sulfur compounds;

wherein the omega-6 fatty acid(s) and antioxidant(s) is not any single specific variety of a vegetable, a fruit, a nut, or a seed.

TABLE OF CONTENTS

Page(s)
(As in original)

TABLE OF AUTHORITIES

Page(s)
(As in original)

CASES

UNITED STATES CONSTITUTION

STATUTES

RULES

STATEMENT OF RELATED CASES

Petition for writ of mandamus from improper Fed.R.Civ.P.12(b)(1) and 12(b)(6) dismissals to the district court was filed in the Supreme Court (case No. 22-228), which was denied review[5] without implicating merits[6]. No other appeals from the action were filed before any appellate court and no related cases are pending in any court in the United States. However, the Federal Circuit's decision in this appeal will influence nearly 36 issued patents and 10 pending patent applications before patent offices, appeal boards, and courts in several jurisdictions[7] related to the underlying patent application in the civil action.

ORAL ARGUMENT REQUESTED

Oral argument is pled because complex and vital issues to constitutional rights to due process and discoveries are raised, in view of poorly understood proportional intake of omega-6 fatty acids and antioxidants including polyphenols, long-felt unresolved need, and public suffering witnessed by the Appellant *firsthand* and public interest from inability of market to solve the problem without limited exclusivity. It will benefit the Court to hear the Appellant in person[8].

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[5]supremecourt.gov/search.aspx?filename=/docket/docketfiles/html/public/22-228.html.

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

[7]asha-nutrition.com/research/intellectual-property/

[8]Appellant has good knowledge of patent laws from prosecuting patent matters through credible law firms in US and abroad, and as pro se for over ten years.

JURISDICTIONAL STATEMENT

The Plaintiff invoked district court's subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 1361, and 35 U.S.C. §145. The court entered summary judgement and final judgement on March 30, 2023, dismissing the case (Appx19-33) while *2nd Am. Complaint* was pending. The very next day on March 31, 2023, the Court denied the motion for leave to file *2nd Am. Complaint* under the pretext the case is dismissed (Appx34). Timely amended notices of appeal from final judgment were filed on April 7, 2023, and June 5, 2023 (ECF.No[9].12; ECF.No.15; Appx14000-14001). Appellant contests all district court's orders upon final judgment. This Court has appellate jurisdiction under 28 U.S.C. §1295(a)(1).

STATEMENT OF ISSUES

1. Whether the district court violated Appellant's due process rights by dismissing,

   a. causes of action to damages and taking without just compensation *arising under* the Fifth Amendment for alleged lack of jurisdiction and sovereign immunity despite invocation of jurisdiction under §1331;

   b. causes of action to bad faith and misconduct, and declaratory and injunctive relief, alleging failure to state a claim while refusing to recognize explicit statements on two full pages of *1st Am. Complaint* and the context of the entire Complaint despite *Ashcroft v. Iqbal*; and

   c. demand for jury trial under Seventh

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[9] Refers to this Court's docket.

Amendment in §1331 action?

2. Whether the district court violated Appellant's due process rights by,

a. placing higher filing burden on the Appellant than the Appellees shortening and eliminating Appellant's response time from paper filings;

b. barring all email and phone communications from the Appellant including on procedural matters related to medical emergency, establishing a new erroneous legal principle contrary to in Fed.R.Civ.P.6(b)(1)(A); and

c. denying discovery enlargement and continuance of the final pre-trial conference to Appellant from illness among Appellant's experts but granting the same relief to Appellees from the same episode of illness?

3. Whether the district court committed harmful legal errors in failing to consider judicially recognized factors under Fed.R.Evid. 104, 402, 403, 405, 406, and 702, *Daubert*, and *Sardis* on admissibility of appellees' expert testimony and failing to exclude the inadmissible testimony?

4. Whether the district court violated Appellant's due process rights and committed harmful error in denying Appellant's motion for leave to file *2nd Am. Complaint* where the amendments seek proper relief from matters already in the original complaint and conform complaint to facts on administrative record and discovery and issues raised about six weeks before in motion for summary judgment?

5. Whether the district court violated Appellant's due process rights in granting the summary

judgment because,

a. close of discovery is under appeal, Appellees' expert testimony is objected, and claims construction and related facts are disputed; and

b. record is rife with disputed facts; while,

c. summary judgment in favor of Appellees fails as a matter of law, at least because claims disclaiming products of nature are patent eligible under §101 and claims drawn to poorly understood factors are not obvious under §103?

6. Whether the district court violated Appellant's due process rights in failing to provide unbiased judges?

STATEMENT OF THE CASE AND FACTS

A. Nature of Action at District Court

The action at district court arises from Defendants' conspiracy to deprive, and bad faith deprivation, of the Plaintiff's rights to her discoveries. The Plaintiff's claims in the action include constitutionally guaranteed exclusive rights to discoveries, recovery of damages due to deprivation of rights in violations of due process and Takings under the Fifth Amendment of the Constitution from unreasonable delay in granting the rights, costs and fees of the action, and declaratory and injunctive relief.

B. Background of the '847 Application

The discoveries described in US Patent Application 13/877,847 ("the '847 application") pertain to precise dosage and proportional requirements of and interactions among omega-6

fatty acids and antioxidants including minor lipids (e.g., polyphenols) and adverse effects of sudden shifts in intake of the substances with profound health effects, such that individualized dosages (specified delivery) have the potential of mitigating chronic diseases and acute health events (such as strokes and heart attacks) and susceptibility to infections (such as COVID-19). (Appx347-422). The claims are directed to the innovative compositions, methods of tailoring, and methods of using the formulations comprising proportional dosages of omega-6 fatty acids and antioxidants including polyphenols in the broadest embodiments with additional features in narrower embodiments (Appx46-59).

The claimed features in the '847 application remain poorly understood in the art even today. 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 the Dietary Guidelines for Americans, U.S.DHHS, or the most authoritative medical school textbooks (Table 3 infra). Scientific and mainstream 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. (Appx7436-7438). Thus, no teaching on substrate ingestion is provided to physicians and/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. ***That* is junk science!**

Plaintiff is directly affected by this failure of prior art from horrific suffering, precipitous decline in health, and demise of her own mother from neural disease without any familial basis (Appx10940). Subsequently, the Plaintiff investigated the matter in early 2000s, and conceived that deficiency of fatty acids critical for brain function, in particular omega-6 fatty acids, and disproportionately high antioxidants in her mother's diet were a significant cause of her progressive symptoms culminating into neural disease diagnosis a decade later. She also conducted experiments in live subjects in patient support groups in various indications, which are reported in her patent applications. (Appx10940-10942).

Appellant took copyrights to make an educational documentary on the subject for public health benefit in 2006-2007, but soon realized due to ***extreme variability*** (as much as 100%) of such substances in natural products, ***complexity*** of varying requirements for individuals (age, gender, diet type, etc.), and ***massive misinformation and disinformation*** in the art on the intake of these substances, a documentary would not be effective. She concluded individualized multi-part preformulated compositions need to be prepared for public health and such solutions would solve multiple public health problems and bring about ***quantum leap of advancement in nutrition and public health.*** To finance and effectively implement the solutions she sought patents, resulting in filing of US

applications 12/426,034 and 13/332,251 (WO 2009/131939) and 13/877,847 (WO 2012051591) between 2008 and 2013. (Appx10942-10943).

C. Conspiracy and Bad faith Deprivation of Rights from '034 Application

Appellees prefer to issue token patents in nutrition, which obstructs advancement in nutrition science, fosters stagnation, and creates more misinformation and disinformation in the art as parties hype their narrow products, compromising public health (Appx10918-10919). Holding scope of inventions against the Appellant, USPTO abused her previous applications 12/426,034 and 13/332,251. Although '251 application was granted, it was after 10 years drag and compromising the patent claims, implementation, and creating bias against Appellant's business. This Court aided Appellees' abuse of the '034 application refusing to answer almost entirety of Appellant's briefs and 100s of evidence documents submitted including testimony from skilled persons in appeal no. 2016-2525. The resulting opinion *In re Bhagat*, 726 F. App'x 772 (Fed.Cir.2018) is a travesty of justice[10], contravening 35 U.S.C. §§ 100(b), 101, and 102, and many of Supreme Court's precedents including *Diamond v. Diehr,* 450 U.S. 175, 188 (1981) (the claims must be considered as a whole), *Bilski v. Kappos,* 561 U.S. 593, 603 (2010) ("process" under §100(b) does not require "transformation"), and *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.,* 569 U.S. 576, 577, 595 (2013) (dictated by nature is not the test). A

[10]Institutions lose credibility when law is differentially applied to the detriment of one party and institutions deteriorate if public does not object.

glaring example of the travesty is the review of claim 102, *solely* rejected under §101:

Table 1	
Opening Brief, 58-59	***In re Bhagat,*** Opinion 11
"Examiner has admitted '*Relative to the compositions of Claims 102, 107, and 119, there does not appear to be a naturally occurring counterpart to all of these elements present together in the claimed combination*'"... Claim 102 recites, "**ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 1:1 to 3:1" and that neither WebWOil (mono:poly 1:2.8) (Appx6985) nor WebOOil (mono:poly 7:1)** (Appx6970) meet the limitation."	Applicant "**has not provided adequate evidence that an oil from different sources would necessarily have a composition that is different** from one from the same source..."[11]

Thus, the Court disregarded *specific composition differences* in ratio of monounsaturated fatty acids to polyunsaturated fatty acids in claim 102 versus cited products. The Court similarly improperly rejected about *55 claims* and denied rehearing[12]. Many patent lawyers (unaffiliated with the Appellant) objected including, Brinckerhoff and Dahle[13],

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

[12] asha-nutrition.com/wp-content/uploads/2018/04/Open-letter-to-USPTO-CAFC.pdf

[13] foley.com/en/insights/publications/2018/03/federal-circuit-finds-composition-of-matter-inelig

Miller[14], Woessner[15], and Graff[16] (Appx13242-13259).

The public and the nation paid the price for atrocious decision in appeal no. 2016-2525 in form of adversity of COVID-19 pandemic on the heels of the case. The '034 application describes viral infections and susceptibility to infections can be mitigated from the disclosed inventions (#2016-2525, J.A. Appx0076, Appx0097) and recent COVID-19 specific investigation upholds Appellants findings and anticipation (Appx7130-7132; Appx7517-7518). Vaccines are useful in emergency, but long-term and broad mitigation of many infectious agents (including agents unknown at present) can be achieved from the implementation of the inexpensive innovations disclosed in the '034 and '847 applications.

The atrocious decision *In re Bhagat* damaged,

(i). the Appellant (ten plus years of Appellant's life, effort, and business was damaged);

(ii). the patent system (though the Opinion was issued as "non-precedential," but it is now patent policy[17]);

(iii). public health (about 1 million Americans die annually of chronic diseases (heart disease, stroke, and diabetes alone)[18], and 1.1 million

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[14]oblon.com/publications/in-re-urvashi-bhagat-one-more-decision-denying-patent-eligibility-of-nature-based-product-claims

[15]natlawreview.com/article/re-urvashi-bhagat-slippery-slope-natural-product-claims

[16]swlaw.edu/sites/default/files/2020-04/6%20Graff_Final.pdf

[17]uspto.gov/web/offices/pac/mpep/s2106.html, uspto.gov/web/offices/pac/mpep/mpep-2100.pdf at 2100-48, and *Koganov, Michael.* 13821775(D) (P.T.A.B. Sep. 30, 2019)

[18]cdc.gov/nchs/fastats/deaths.htm

Americans died of COVID-19[19]);

(iv). US economy ($4.1 trillion in annual health care cost of chronic diseases[20] and $14 trillion total cost from COVID-19[21]);

(v). guideposts for lower courts (e.g., violations in present action); and

(vi). this Court's, judiciary's, and the US government's credibility[22].

The Appellant has vociferously objected[23] for the foregoing reasons.

D. Conspiracy and Bad faith Deprivation of Rights from '847 Application

Appellees' violations of the Appellant's rights became more tyrannical after abuse of '034 Application. Extensive discussion of conspiracy and bad faith deprivation of Appellant's patent rights

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[19]covid.cdc.gov/covid-data-tracker/#datatracker-home

[20]cdc.gov/chronicdisease/about/costs/index.htm

[21]healthpolicy.usc.edu/article/covid-19s-total-cost-to-the-economy-in-us-will-reach-14-trillion-by-end-of-2023-new-research/.

[22]Substantially same claims were granted in 14 countries including Japan, Canada, and South Korea, albeit belatedly because initially they mimicked US actions (asha-nutrition.com/research/intellectual-property/).

[23]https://asha-nutrition.com/wp-content/uploads/2018/09/180829-US2009-Cert-Petition-.pdf, asha-nutrition.com/wp-content/uploads/2019/09/190628Bhagat_SCOTUS_Petition-cert-RFR-final.pdf, asha-nutrition.com/news-media/gallery/, asha-nutrition.com/wp-content/uploads/2019/09/190811LetterToCongress_w_Annexes-compressed.pdf, asha-nutrition.com/wp-content/uploads/2020/06/Doc4-200601-MandRFR2-FINAL-w-APPENDIX.pdf, asha-nutrition.com/wp-content/uploads/2020/06/Doc7-200603-Letter-to-Justices.pdf

from the '847 application is provided in the *1st and 2nd Am. Complaints* filed at the district court (Appx298-299, 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 disclaimer of natural products to force §101 rejections;
- Refusing to recognize and answer arguments and evidence;
- Senior USPTO officers instructing the examiner to arbitrarily narrow the scope of the claims and necessitating mixing all ingredients in one container that could even harm public health from interactions;
- Refusing to enter expert testimony on record so it would not be available for appeal review;
- Rejecting claims under the pretext of 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.

Appellant did her utmost to avoid the expensive civil action begging the Chief Judge of Patent Trial and Appeal Board (PTAB) to fairly decide the matter in five petitions, but to no avail (Appx11016-11017). Section 145 action had to be filed at the district court

because the Defendants had refused to enter expert testimony on record. During the ***15 years*** of abuse since the Appellant's first application was filed in 2008, the Defendants have caused enormous damage to Appellant's life and business, making the demand for damages and just compensation for Taking necessary.

E. Procedural History at District Court

Table 2 below provides a snapshot of the main proceedings at district court.

<table>
<tr><td colspan="6">Table 2
Filing (submission) [docketing] Dates[24]</td></tr>
<tr><td colspan="6">Original Complaint 12/9/20 (12/8/20) [12/10/20]</td></tr>
<tr><td colspan="6">1st Am.Complaint 4/19/21 (4/17/21)</td></tr>
<tr><td>Appellees' FRCP 12(b)(1), 12(b)(6) Motion to Dismiss</td><td>Motion 5/3/21</td><td>Oppositio n 5/24/21 (5/22/21)</td><td>Reply 6/1/21</td><td>Opinion Order Grante d 7/22/21</td><td>Notice of Mandamus 8/3/21 (7/31/21) [8/4/21]</td></tr>
<tr><td colspan="6">Answer 8/5/21</td></tr>
<tr><td colspan="6">Appellant's Motion for Stay Pending Mandamus Denied 4/12/22</td></tr>
<tr><td colspan="6">Scheduling Order 7/11/22 (setting Close of discovery to 12/9/22 and Final pretrial conference to 12/15/22)</td></tr>
<tr><td colspan="6">Final Joint Discovery Plan 8/11/22</td></tr>
<tr><td colspan="6">Scheduling Order 8/11/22 (adapting joint discovery plan)</td></tr>
<tr><td colspan="6">Mandamus Petition Not Accepted for Review 10/31/22</td></tr>
<tr><td>Appellant's</td><td>Emails &</td><td>Order</td><td>Objections</td><td>Order</td><td>Notice of</td></tr>
</table>

[24]Appellant is prohibited from electronic filing, creating up to 10-day delay in docketing for court review. Filing date for Appellant refers to district court mail room receipt date, submission date in () refers to the date Appellant dispatched and emailed the material to the court clerk, and docketing date (if different from filing date) in [] refers to the date the clerk entered the matter on the docket for the case.
The relevant dates can be found in the Civil Docket Report (Appx35-45), although it has some errors in filing versus docketing dates.

Requests for Conference Call for Discovery Enlargement	Calls 11/20-22/22 12/1/22 12/5/22	**Barring** Emails & Calls 12/16/22	12/21/22 (12/19/22) [12/22/22]	**Denied** 12/30/22	Appeal 1/13/23 (1/10/23) [1/17/23]
Appellees' Motion for Discovery Enlargement	Motion 12/5/22	Opposition None	Reply None	Order **Granted** 12/6/22	
Appellant's Motion for Discovery Enlargement	Motion 12/14/22 (12/11/22) [12/15/22]	Opposition 12/16/22	Reply 12/21/22 (12/19/22) [12/22/22]	Order **Denied** 1/10/23	Notice of Appeal 1/13/23 (1/10/23) [1/17/23]
Appellant's Motion Disqualification of Appellees' Expert	Motion 12/14/22 (12/11/22) [12/15/22]	Opposition 12/19/22	Reply 12/28/22 (12/22/22) [12/29/22]	Order **Denied** 1/17/23	Notice of Appeal 1/30/23 (1/26/23) [2/1/23]
Appellees' Motion for Summary Judgment	Motion 1/20/23	Motion to Strike/Stay 1/31/23 (1/30/23) [2/1/23]	Opposition 2/6/23 Reply 2/9/23 (2/7/23) [2/13/23]	Order MSJ **to be Granted** 2/27/23 Order MSJ **Granted** 3/30/23	Notice of Appeal 2/28/23 and 4/6/23 (3/30/23)
Appellant's Motion for Leave to File *2nd Am. Complaint*	Motion 3/15/23 (3/13/23) [3/22/23]	Opposition 3/22/23	Reply 3/28/23 (3/27/23) [3/29/23]	Order **Denied** 3/31/23	Notice of Appeal 4/7/23 (3/31/23) [4/10/23]

SUMMARY OF ARGUMENT

Fifth Amendment of the U.S. Constitution provides "due process of law." "Due process of law requires that the proceedings shall be fair." *Snyder v. Com. of Mass.*, 291 U.S. 97, 116, 137 (1934). Regrettably, the district court failed to provide fair proceedings violating Appellant's due process rights

across the board. For the reasons, fully elaborated infra, reversal of nearly all of district court's decisions and orders is required.

I. Dismissal of causes of actions for damages and costs for due process violations in bad faith examination and Taking from regulatory delay should be reversed because district court has jurisdiction under well-paired statutes 28 USC §§ 1331, 1338(a), and 35 USC §145 invoked and sufficiently stated in *1st Am. Complaint* and supplemented in *2nd Am. Complaint.* See *United States v. Testan, FHA v. Burr, FDIC v. Meyer, First English, Bell Atlantic, Ashcroft, and Estelle* discussed infra. Appellant's right to jury trial under Seventh Amendment in the §1331 action should be restored.

II. Denial of discovery enlargement should be reversed under *Newell, Fitzpatrick,* and *Datascope* standards, because district court procedural errors placed higher litigation burden on Appellant, denied legal provision under Fed.R.Civ.P.6(b)(1)(A) to Appellant, and denied discovery enlargement to Appellant while granting it to Appellees, from Appellant's suffering, unfairly affecting the outcome.

III. This Court must reverse admission of Harris testimony because the district court committed harmful legal errors in failing to make relevancy and reliability determinations required by Fed.R.Evid. 702 and *Daubert* despite repeated reprimands from Advisory Committee on Rules and appellate courts. Each of *Garcia, Sardis, Gen. Elec., Burkhart, Hall,* and *Wickersham* require this Court to exclude Harris testimony replete with analytical gaps.

IV. Denial of entry of *2nd Am. Complaint* should be reversed under *Foman*, *Pittston*, *Johnson*, and *Edwards* standards because the amendments sought seek proper relief from matters already in the original complaint and clarify jurisdiction, supplement facts from administrative record, and conform complaint to discovery and issues raised about six weeks before in motion for summary judgment. It is a manifest injustice to deny the amendments for proper relief.

V. Summary judgment should have been withheld because of pending appeal, objected testimony, and record rife with disputed facts per Fed.R.Civ.P.56(a)-(c). Nonetheless, summary judgment as to unpatentability fails as a matter of law under *Abbott, Markman, Alice, Mayo, Graham, Continental, Ruiz, ATD, Ormco,* and *Loctite* standards, because Appellant's patent claims disclaim products of nature and are drawn to poorly understood factors and solve critical unmet need. The judgment should be reversed and ordered in favor of Appellant on patentability.

VI. This Court should consider just and suitable relief for district court's failure to provide unbiased judges in the proceedings considering consistent refusal to consider Appellant's pleadings and briefs and reflexive denial of relief.

STANDARD OF REVIEW

In patent appeals, this Court applies the law of the regional circuit, here the Fourth Circuit, to issues not unique to patent law. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1365 (Fed.Cir.2018). The Fourth Circuit reviews *de novo* both questions of statutory

interpretation, *United States v. Abugala*, 336 F.3d 277, 278 (4th.Cir.2003), and legal determinations, *El-Masri v. United States*, 479 F.3d 296, 302 (4th.Cir.2007). Standard of review applicable to specific issues is provided before the argument in the following section.

ARGUMENT

I. DUE PROCESS VIOLATIONS IN DISMISSING CAUSES OF ACTION AND JURY TRIAL DEMAND

A. Standard of Review

A decision on a motion to dismiss under Fed.R.Civ.P.12(b)(1) for lack of subject matter jurisdiction is an issue of statutory interpretation reviewed with plenary determinations. *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1325 (Fed.Cir.1998). A decision on a motion to dismiss under Fed.R.Civ.P.12(b)(6) for failure to state a claim upon which relief can be granted is an issue of law reviewed *de novo*. *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1134 (Fed.Cir.1995). This Court reviews Seventh Amendment constitutional right to jury trial as a matter of law. *In re Lockwood*, 50 F.3d 966, 969-970 (Fed.Cir.1995).

B. District Court Violated Appellant's Right to Justice in Dismissing Causes of Action to Damages and Taking

District Court has Jurisdiction to Try Damages from Due Process Violations:

The opinion below improperly states, "Congress has not waived its sovereign immunity for money

damages in actions brought pursuant to 35 U.S.C. S 145," (Appx2-3), because Appellant expressly invoked jurisdiction under well-paired statutes 28 USC §§ 1331, 1338(a), and 35 USC §145 (Appx304) for damages for due process violations in bad faith examination, just compensation for regulatory delay, and to obtain patent (Appx298-300), and so emphasized in opposition to dismiss asserting statutes can be paired for money damages per Supreme Court precedent in *United States v. Testan*, 424 U.S. 392, 398 (1980) (Appx542-547; Appx524-619). Further, Fed.R.Civ.P.8 merely requires, "a short and plain statement of the grounds for the court's jurisdiction," not citation of statute, which can be inferred from the explicit statements in the pleading.

Here expressly invoked §1331 ***specifically*** confers jurisdiction upon district courts for significant federal interest and constitutional standing matters providing, "The district courts shall have original jurisdiction of ***all*** civil actions arising under the Constitution, laws, or treaties of the United States," i.e., not some or most—but ***all***. Further, the Historical Revisions and Editorial Notes to §1331 confirm 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 subject matter jurisdiction for the 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 Plaintiff's life and business from violation of due

process of law and Taking of Plaintiff's property without just compensation under the Fifth Amendment, that is likely to be redressed by a favorable judicial decision. The action properly seeks monetary relief under §1331, U.S. Const. Article I, Section 8, Clause 8, and the Fifth Amendment's Due Process and Takings clause. Rights to discoveries are "property for purposes of the Due Process Clause or the Takings Clause." *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1379 (2018).

The Supreme Court has repeatedly held "when a federal court has jurisdiction, it also has a 'virtually unflagging obligation . . . to exercise that authority.'" *Mata v. Lynch*, 576 U.S. 143, 150 (2015).

Further, *FHA v. Burr*, 309 U.S. 242, 245-246, 250 (1940) held, "when Congress establishes such an agency, authorizes it to engage in commercial and business transactions with the public, and permits it to 'sue and be sued,' it cannot be lightly assumed that restrictions on that authority are to be implied," "that agency is not less amenable to judicial process than a private enterprise under like circumstances would be," and "Waivers by Congress of governmental immunity from suit in the case of such federal instrumentalities should be construed liberally." *Id.* 245-246, 250. Furthermore, in *FDIC v. Meyer*, 510 U.S. 471, 475 (1994) Supreme Court upheld its ruling in *FHA v. Burr* stating, "Because the claimant in each of these cases was seeking to hold the agency liable just like "any other business," [Federal Housing Administration, Franchise Tax Board, and U.S. Postal Service], it was only natural for the Court to look to the liability of private

businesses for guidance. It stood to reason that the agency could not escape the liability a private enterprise would face in similar circumstances." *Id.* 482-483.

USPTO is clearly a "sue-or-be-sued" agency, which is spelled out in 35 U.S.C. §145 providing "remedy by civil action." Congress' intent in §145 leaves the possibility of money damages, unlike 5 U.S.C. §702 providing "relief other than money damages." Thus, §145 can be paired with other statutes for money damages, such as §1338(a) and §1331, as Appellant did in the *1st* (and *2nd*) *Am. Complaint.*

District Court has Jurisdiction to Try Compensation for Regulatory Taking:

The opinion below improperly states,

> "The Tucker Act waives sovereign immunity with respect to non-tort monetary damage claims, such as violations of the Takings Clause of the Fifth Amendment, against the United States. But "a claim for just compensation under the takings clause must be brought to the Court of Federal Claims in the first instance." *E. Enters. v. Apfel*, 524 U.S. 498, 520 (1998)." (Appx3)

Title 28 U.S.C. §1491 ***does not mention specific or exclusive*** jurisdiction to the Court of Federal Claims to render judgment on the Fifth Amendment's Due Process or Takings clauses. Waiver of sovereign immunity is ***self-executing*** in Constitutional provision for just compensation for Takings, such as when regulation goes too far. See *First English Evangelical Lutheran Church v. Cnty. of Los Angeles*, 482 U.S. 304, 314-316 (1987); *San*

Diego Gas & Elec. Co. v. City of San Diego, 450 U.S. 621, 654 (1981) (Brennan, J., dissenting); *Jacobs v. United States,* 290 U.S. 13, 15 (1933). Further, there is ***judicial economy*** in adjudicating the causes to damages and Taking with §145 action because the causes are interrelated and interdependent.

In 2019, Supreme Court clarified "Tucker Act is not a prerequisite to a Fifth Amendment takings claim," stating "A party who loses a Tucker Act suit has nowhere else to go to seek compensation for an alleged taking," and opined that parties could pursue takings claims in federal courts. *Knick v. Township of Scott*, 139 S. Ct. 2162, 2174 (2019). *Knick* cancels inapposite decision in *E. Enters.*, a splintered decision on an unrelated matter (unconstitutional Congressional Act), which led to circuit split. *McCarthy, et al. v. City of Cleveland*, 09-4149 (6th.Cir.2010)[25]. The Solicitor General also argued in *Knick* as amicus curiae advising the Supreme Court "inverse condemnation claims 'aris[e] under" federal law and can be brought in federal court under §1331 through the *Grable* doctrine. See *Knick* brief for United States as *Amicus Curiae* 22–24. Previously also in *Duke Power Co. v. Carolina Environmental Study Group*, 438 US 59, 71 (1978) Supreme Court held, a Takings claim can be brought under §1331 federal question jurisdiction.

Accordingly, the District Court erred in dismissing the monetary damages claim and Takings claim because the court has jurisdiction at least under well-paired statutes, 28 U.S.C. §§ 1331,

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[25] https://caselaw.findlaw.com/court/us-6th-circuit/1544179.html at 7.

1338(a), and 35 U.S.C. §145; §1331 is legislated to include actions against the United States and its agencies without limitation on the amount; USPTO is a "sue and be sued agency" waiving the agency's sovereign immunity; sovereign immunity does not shield bad faith actions of the government; and a waiver of sovereign immunity for Taking claims is unnecessary.

C. District Court Violated Appellant's Right to Justice in Dismissing Causes of Action to Bad Faith Deprivation of Constitutional Rights to Discoveries and Declaratory and Injunctive Relief Refusing to Recognize Most of the Complaint

The opinion below improperly states,

> "The [1st] Amended Complaint includes no facts supporting the conclusion that the USPTO violated Plaintiff' s constitutional rights," "that the USPTO made false statements or acted with misconduct," and "that Plaintiff is plausibly entitled to mandamus relief." (Appx5-6).

In stating the foregoing, the district court refused to recognize the entirety of the Complaint, specifically the immediate context in: (1) paragraphs 2-3, 36-37, 40-41, 45, 48-49, 55, and 56-63 providing facts that the right to patents is grounded in the US Constitution, which was violated by USPTO bad faith objections, refusal to recognize arguments and evidence submitted, refusal to enter evidence on record, and misconduct and false statements ***contradicting the record***; (2) paragraphs 11 and 46 asserting USPTO has tried to force Appellant to accept an extremely narrow patent which would have

compromised the innovations; and (3) paragraph 13 and Prayer for Relief (b), (c), (d), and (f) specifying declaratory and injunctive relief requested (Appx298-318). Further, the allegation of lack of plausibility is hollow because having exclusive jurisdiction over §145 the court ***knows administrative record contains full prosecution history.*** Furthermore, by dismissing the causes of action the court ***foreclosed*** revealing of evidence in discovery and complaint amendments, particularly in response to ***new defenses*** raised (new grounds of rejection and new art citations) by Appellees, necessitating ***new reasons*** for declaratory, injunctive relief, and mandamus relief. (Appx10952-10957; Appx11022-11023).

Thus, the district court refused to honor each of the following pleading standards: Fed.R.Civ.P.8(a)(2) and (e) requiring "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."

Further, the district court disregarded the Supreme Court instruction to construe pro se pleadings liberally. *Estelle v. Gamble,* 429 U. S. 97, 106 (1976).

Furthermore, the district court's unfairness and prejudice against Appellant in dismissing the causes

of action is confirmed by denial of motion to file *2nd Am. Complaint*, which provides ***extensive citations to administrative record supporting the conclusion the USPTO violated Plaintiff's constitutional rights***, USPTO's misconduct and false statements, and provides specific reasons and form of necessary declaratory, injunctive, and mandamus relief (Appx10984-11015; Appx11022-11023). Thus, the district court made excuses to violate the Plaintiff's rights.

Therefore, the dismissal of causes of actions should be reversed, because (1) the court refused to recognize the facts before it, (2) the court refused to apply the correct legal standard, and (3) the court refused to accept complaint amendments providing further facts and reasons for the requested relief.

D. District Court Refused to Recognize Seventh Amendment Right to Jury Trial Under §1331

The U.S. Constitution Seventh Amendment language puts forth right of trial by jury not as suggestion but a requirement, and any fair examination of the history reveals the substitution of government agencies for juries is flatly unconstitutional. Also see Fed.R.Civ.P. 38, 39, and 28 U.S.C. §1861.

Suits against government for money are commonly tried by jury, if demanded. *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).

There is no bar in 28 U.S.C. §§ 1331, 1338(a) and 35 U.S.C. §145 for jury trial. The USPTO is a "sue and be sued" agency that should be held to the same

standards as a private corporation, as per Supreme Court precedents. *FHA v. Burr* 245-246, 250 and *FDIC v. Meyer* 482-483. Therefore, the Appellant has a right to jury trial as it would against a private enterprise.

The striking of jury trial should be reversed, especially because the district court demonstrated bias failing to provide fair proceedings discussed in this paper.

II. DUE PROCESS VIOLATIONS STACKING PROCEDURE AGAINST UNREPRESENTED PARTY VIOLATING EQUAL ACCESS TO JUSTICE AND EQUAL PROTECTION OF THE LAWS UNFAIRLY AFFECTING OUTCOME

A. Standard of Review

Procedural errors that unfairly affect the outcome cannot be ignored. *Newell Co. v. Kinney Mfg. Co., 864 F.2d 757, 765* (Fed.Cir.1988). Appellate court will not defer at all in cases when the trial tribunal establishes a new legal principle. *Fitzpatrick v. Bitzer*, 427 U.S. 445, 449-50, 456 (1976). "[a] manifest or clear error of judgment occurs 'only if we `come close to finding that the trial court had taken leave of its senses." *Datascope Corp. v. SMEC, Inc.*, 879 F.2d 820, 828 (Fed.Cir.1989).

B. District Court Violated Appellant's Right to Equal Access to Justice Differentially Requiring Paper Filings from Appellant Reducing Her Discovery Time by About 10% Unfairly Affecting the Outcome

The district court prohibits unpresented parties,

as the Appellant, from electronic filing and communications without motion[26]. The Appellant complied with paper procedure utilizing express delivery service throughout the proceedings and alerted the court via emails including delivery tracking information to expect the paper filings. However, the usurpation of time in printing (such as for large filing of over 500 pages) and dispatch, delay in transit[27] and docketing (Table 2 supra), and docketing errors by clerk requiring ***more*** paper filings for correction has been ***unfair*** to Appellant (Appx670, Appx8187-8188), especially because of short discovery of four months and short motion schedule requiring quick response and hearings within 1-3 working days (Appx6954, Appx6957-6958). Provision for printing, dispatch, and transit at times leaves no time for substantive drafting. Additionally, over the course of litigation, cumulative extra time taken in paper filings shortens time available for substantive matters. Appellant estimates during the scheduled discovery period from August 10, 2022, to December 9, 2022, about ***12 days or 96 hours*** were usurped due to paper filings (printing, dispatch, follow up to ensure receipt and prompt docketing, and requests to correct docketing errors, without counting transit time and docketing delays) (Table 2 supra). Consequently, Appellant was provided about ***10% less discovery time*** than Appellees. Unrepresented parties are generally given extra time for drafting (Local Rule 7(K)[28]), but

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[26]vaed.uscourts.gov/sites/vaed/files/EDVACOMPLETEProSeHandbook_7-26-22.pdf (7, 14).

[27]Appellant is located 3000 miles from the court.

[28]https://www.vaed.uscourts.gov/sites/vaed/files/Local%20Rules%20EDVA%20Jan%2018%202023.pdf

here the district court gave less time to the pro se Appellant.

Further, as evidenced by Table 2, Appellant's paper filings are filed (received in mailroom) up to 6 days after dispatch (exacerbated by Holidays and weather[29]) and docketed up to 7 days after receipt. As a result, some of Appellant's filings were made available to court after the hearing (Appx38-39, compare #53 with #57) or late, e.g., *2nd Am. Complaint* dispatched on March 13, 2023, was received in mail room on March 15, 2023 and docketed on March 22, 2023 (Appx43-44).

Appellant objected to the differential paper filing requirements and requested the court should either permit her to file electronically or allow her to email the documents to the clerk for docketing for equal access to justice (Appx8186-8188), but the requests were denied (Appx11-12) in ***manifest injustice*** (Fed.R.Civ.P.16(e)).

During the scheduled pre-trial discovery period, the approximately 12-day cumulative usurpation of Appellant's time due to paper filings unfairly affected the outcome because of progressive delay of series of substantive matters, including,

- precluded Appellant's timely completion of discovery (discussed infra);
- impeded her full opposition to motion for summary judgement (discussed infra); and
- delayed the filing of her motion for *2nd*

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29 https://en.wikipedia.org/wiki/December_2022_North_American_winter_storm

Am. Complaint (discussed infra).

Therefore, the differential paper filing requirement by the district court is manifest injustice, it ***unfairly affected the outcome***, it cannot be ignored. *Newell* 765. This Court must reverse and remand with an order to enlarge discovery and to either accept electronic or email filings from Appellant going forward or proportionately extend discovery and motion schedule for her.

C. District Court Established a New Erroneous Legal Principle Contrary to Fed.R.Civ.P. 6(b)(1)(A) Refusing to Accept Appellant's Oral and Email Requests for Discovery Conference Call Unfairly Affecting the Outcome

November 20-22, 2022, Appellant telephoned and emailed the district court informing the court of ***medical emergency*** of one of her experts, requesting conference call with Appellees to enlarge discovery because paper motions would not reach the court in time to obtain ruling on the matter before the expert rebuttals ***due on November 25, 2022*** (November 24th being Thanksgiving). The emails also notified the court discovery close of December 9, 2022, and Final Pretrial Conference of December 15, 2022, also needs to be discussed in the conference call due to the illness and discovery abuses by Appellees. Receiving no response, the Appellant called and emailed the court again December 1st and 5th informing the court of ***second medical emergency*** in family of Appellant's second expert, requesting conference call and stressing paper motion will not enable resolution before ***discovery close on December 9, 2022***. (Appx7292-7294). She also notified the Appellees of

her requests to the court to set a conference call for discovery enlargement.

Magistrate Judge responded to Appellant's email and phone requests for conference call on December 16, 2022, with order barring ***all*** email and phone communications from the Appellant (Appx9-10).

Appellant objected to the order in accordance with Fed.R.Civ.P.72(a) and 28 U.S.C. §636(b)(1)(A) within 14 days (Appx8188-8189) asserting,

(i) Fed.R.Civ.P.6(b)(1)(A) provides "the court may, for good cause, extend the time" "with or without motion or notice if the court acts, ***or if a request is made***, before the original time or its extension expires", therefore law provides that a request ***can be made*** without paper motion for good cause (see similar provision in Local Rule 26(B)); and

(ii) Fed.R.Civ.P.83 requires local rule must be consistent with federal rules therefore, the order requiring ***all*** requests on paper is erroneous violating Fed.R.Civ.P.6(b)(1)(A) and 83.

However, contrary to Fed.R.Civ.P.72(a) and 28 U.S.C. §636(b)(1)(A), which require ***district judge*** in the case must consider timely objections and modify or set aside any part of the order that is clearly erroneous or is contrary to law, Magistrate Judge issued another order on December 30, 2022, upholding the previous order. (Appx11-12).

Fed.R.Civ.P.6(b)(1) provides the district court discretion to extend time, but Fed.R.Civ.P.6(b)(1)(A) ***requires accepting the request*** for good cause without filing a paper motion before the due date. The district court orders (Appx9-12) establish a new

legal principle violating Fed.R.Civ.P.6(b)(1)(A).

Supreme Court has directed appellate courts to ***not defer at all*** in cases when the trial tribunal establishes a new legal principle. *Fitzpatrick* 449-50, 456. Accordingly, this Court must decide without deferral whether district court order barring ***all*** email and phone communications, even in emergency, contravene 28 U.S.C. §2071 and Fed.R.Civ.P.6(b)(1)(A) and 83.

Further, the error by the district court in establishing a new legal principle contravening Fed.R.Civ.P.6(b)(1)(A) did ***unfairly affected the outcome*** because the district court refused to recognize timely requests made by emails and telephone for good cause, subsequently denied the paper motion under the pretext of untimely and lacking excusable neglect (Appx13-15), therefore the error cannot be ignored as per *Newell* 765. This Court must reverse and remand with an order to accept timely oral and email motions for good cause and enlarge discovery.

D. District Court Has Lost Senses—Discovery Enlargement Stemming from Medical Emergency Among Appellant's Experts Was Granted to Appellees but Denied to Appellant—Unfairly Affecting the Outcome

This Court said in *Datascope* "a manifest or clear error of judgment occurs 'only if we `come close to finding that the trial court had taken leave of its senses." *Id.* 828. Here the district court has clearly lost its senses, having buried the Appellant under extra paper filing burden (discussed supra) and rebuffed her timely emails and phone calls for

discovery conference call for good cause/extraordinary circumstances of medical emergency, and in face of demonstration that the discovery schedule cannot be met despite her diligence (Appx8222-8230), enlarged discovery for the Appellees on account of illness among ***Appellant's*** experts but ***denied same relief to Appellant*** under the pretext that paper motion was late and good cause (diligence) was not shown largely refusing to recognize the diligence shown in the paper motions (Appx13-15).

On November 20, 2022, Appellant's expert Dr. Kent Erickson was in emergency room for chest pains and related issues, and on November 27, 2022, her expert Dr. Undurti Das had to leave for India to provide his wife immunotherapy infusions that he could better administer in India (Appx7286).

On December 5, 2022, the Appellees filed unopposed motion for 30-day enlargement of discovery to depose Dr. Das. The district court promptly granted the motion the ***very next day*** on December 6, 2022, extending close of discovery to January 6, 2023, and continuing the final pre-trial conference to January 12, 2023 (Appx39).

Because Appellant's November 20-December 5 emails and calls for conference call to discuss discovery enlargement were rebuffed, on December 11, 2022, she dispatched and emailed paper motion to court (filed on December 14th and docketed on December 15th) for 13-day extension of time from November 25, 2022 to disclose rebuttals to Defendants' expert report, and 60-day discovery enlargement from December 9, 2022 to complete discovery (meet and confer, compel discovery, and

take depositions) because **(1)** illness among Appellant's experts, **(2)** extra time required in paper filings (discussed supra), and **(3)** discovery abuses by Appellees (111-pages forced expert report mutilating claims and massively reconstructing prior art, and extensive objections to written discovery) had prevented Appellant from completing discovery, despite her diligence (Appx7275-7288).

Appellant provided the district court a proposed order with blank spaces where the district court could insert ***narrower*** discovery enlargement such as less than 60 days (Appx7271).

On December 16th the district court issued the order barring all email and calls from the Appellant citing her motion for enlargement and email requests (Appx9-10). Subsequently, the court waited ***26 days*** and on January 10, 2023, at about 4pm EST, ***1 day before*** the final pre-trial conference on January 12, 2023 at 10am, issued the order denying discovery enlargement and continuance of final pre-trial conference knowing full well that last-minute order would make it impossible for the Appellant located on the west coast to prepare for and attend the pre-trial conference on the east coast (Appx13-16). Waiting 26 days until the last day to issue the order is another example of stacking procedure against the unrepresented party.

Thus, in accordance with Fed.R.Civ.P.6(b)(1)(A) and 16(b)(4), and Local Rules 16(B) and 26(B), Appellant timely requested discovery conference by email and telephone November 20-22, and December 1-5, 2022, *before* November 25th and December 9th deadlines, dispatched paper motion on December 11, 2022, demonstrated diligence in executing discovery

from July 2022 to December 9, 2022, worked round the clock and met most deadlines, and demonstrated that the schedule "cannot reasonably be met despite the diligence of the party seeking the extension," (Appx8220-8229) which is good cause to modify the schedule. Fed.R.Civ.P.16 Advisory Comm.'s Notes (1983 Amendment); and *Cook v. Howard*, 484 F.App'x 805, 815 (4th.Cir.2012).

The district court lost its senses and was unfair,

(1) in waiting till the last day before final pre-trial conference to issue the order on discovery enlargement; and
(2) in denying discovery enlargement to Appellant while granting to Appellees although Appellant had to endure medical absence of her experts and had worked diligently to meet the oppressive burdens placed on her by the Appellees and the court.

The district court's actions unfairly affected the outcome, in that Appellant could not attend the final pre-trial conference and discover further information from written and oral discovery necessary for trial preparation.

Therefore, the district court clearly erred, and the errors cannot be ignored because they unfairly affected the outcome. *Datascope* 828; *Newell* 765. Therefore, this Court must reverse and remand with an order to enlarge discovery by 60 days, or as considered just and reasonable by this Court.

III. DUE PROCESS VIOLATIONS IN FAILING TO CONSIDER JUDICIALLY RECOGNIZED FACTORS TO EXCLUDE APPELLEES' EXPERT TESTIMONY, FAILING TO

EXCLUDE THE INADMISSIBLE TESTIMONY, COMMITTING HARMFUL LEGAL ERROR

A. Standard of Review

Fourth Circuit, reviews "district court's decision [] on the admissibility of expert testimony for abuse of discretion." *McKiver v. Murphy-Brown, LLC*, 980 F.3d 937, 958 (4th.Cir.2020). "[W]e review a district court's abdication of its gatekeeping role for harmless error and require a new trial 'only when the admission of evidence affected the substantial rights of a party.' *Wickersham v. Ford Motor Co., 997 F.3d 526, 531 (4th.Cir.2021)*." *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 283 (4th.Cir.2021).

B. Admission of Harris Testimony Must Be Reversed Because District Court Committed Harmful Legal Errors in Failing to Make Relevancy and Reliability Determinations Required by Fed.R.Evid.702 and *Daubert*

With her motion to disqualify Dr. Harris, Appellant presented strong grounds for ***inadmissibility*** with about 33-page briefing and about 500-page evidence (Appx7298-7304; Appx7309-7762; Appx8241-8292; Appx8297-8299)[30], asserting, "Dr. Harris' opinions and testimony ***lack any indicia of admissibility*** under *Daubert* [*v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993)] and the Federal Rules of Evidence 104, [402], 403, 405, 406, and 702"

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[30] It is not possible to list all facts here because of the word limit imposed on this brief, the number of issues on appeal, and the denial of request to enlarge the brief (ECF.No.16). The Court is requested to refer to briefing and evidence submitted to the district court for further details.

(Appx8242) including:

1. *Inadmissible for Irrelevance and Unreliability Under Fed.R.Evid. 702:* Dr. Harris has significant conflict of interest and financial interest in testifying against the patentability of '847 application. His company OmegaQuant (https://omegaquant.com/about/, https://omegaquant.com/shop/) operates in the same space and he draws consulting income from several companies that market fatty acids. His opinions tainted by self-interests are *irrelevant and unreliable.*

2. *Inadmissible for Failing All Fed.R.Evid. 702 Tests:* Harris testimony (a) will not help the trier of facts to understand facts, (b) is not based on sufficient facts or data, (c) is not product of reliable principles or methods, and (d) has not reliably applied the principles and methods to the facts. The testimony is ***fausse*** as he failed to recognize multiple explicit disclosures and claimed limitations in the '847 application, he massively reconstructed and culled prior art to allege obviousness (Appx8264-8292), ***his testimony contradicts his own published statements post-2010 stating omega-6 fatty acids, antioxidants, and phytochemicals intake are poorly understood*** (Appx7695-7714) he contradicted himself within his testimony, and he did not assess secondary considerations for obviousness analysis.

3. Inadmissible for Failing Fed.R.Evid.402 Test "Irrelevant evidence is not admissible:" Harris testimony is irrelevant because he imposes his interpretation of law on assessment of priority, claim interpretation, obviousness, and unexpected results.

4. Inadmissible for Failing Fed.R.Evid.403 Tests: Harris testimony creates unfair prejudice because it misleads and seeks to sow confusion by mutilating each of Plaintiffs disclosure, claims, state of the prior art, and the law. It has caused and will cause further undue delay and waste of time. Appellant's ***unpaid*** experts have declared Harris testimony to be "insincere", "illogical", "absurd", "misrepresent[ations]", "offensive", "lack[ing] application of mind", and "dishonest." (Appx8255). Therefore, harm from admission of Harris testimony significantly outweighs any probative value.

5. *Inadmissible for Failing Fed.R.Evid.405-406 Tests*: Dr. Harris has a habit of issuing opinions motivated by financial interests[31], without regard to public health. He has promoted high omega-3 and high antioxidant intake most of his career which the '847 application teaches against, and ***he admitted in his post-2010 publications that omega-6, antioxidants, and phytochemical intake is not well-understood*** (Appx7695-7714) (correct dosages of which are taught and claimed in the '847 application), yet, in his paid subject testimony he did a complete about-face from his published opinions to allege the claims as obvious (Appx7464-7466; Appx7592-7594).

Without responding to the arguments contesting admissibility, failing to consider judicially recognized

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[31]Dr. Harris was also part of Health Diagnostics Laboratory (HDL) (7716), and his company OmegaQuant sold research assays to HDL (en.wikipedia.org/wiki/William_S._Harris), and HDL is known to have bribed doctors to send business their way (https://www.medpagetoday.com/publichealthpolicy/ethics/59098).

factors constraining its exercise of discretion, and without providing factual and legal reasons for the conclusion, the district court denied the motion to exclude Harris testimony in a single sentence, ***making no relevancy and reliability determinations***, relegating entirety of Appellant's arguments to "weight of the expert's testimony, not admissibility," (Appx17) despite that Appellant challenged both relevancy and reliability of Harris testimony.

According to series of precedents Harris testimony should be excluded, including *Garcia v. Johanns*, 444 F.3d 625, 635 (D.C.Cir.2006) (rejecting statistical analyses as "analytically flawed because they did not incorporate key relevant variables connecting disparate impact to loan decisionmaking criteria"); *Sardis* 290 and *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."); *Burkhart v. Wash. Metro. Area Transit Auth.*, 112 F.3d 1207, 1213-14 (D.C.Cir.1997) (affirming exclusion of expert [], because it constituted an impermissible legal conclusion); and "The burden of laying a proper foundation for the admissibility of an expert's testimony is on the party offering the expert, and the admissibility must be shown by a preponderance of the evidence." *Hall v. United Ins. Co. of America*, 367 F.3d 1255, 1261 (11th.Cir.2004) (citation omitted) (incorporated in Fed.R.Evid.702 itself effective December 2023). See

Corrected Prior Art Tables demonstrating analytical gaps in Harris opinion (Appx8264-8292).

Fed.R.Evid.702 and *Daubert* require district judges to perform, a "gatekeeping role" to determine whether proposed expert testimony "rests on a reliable foundation and is relevant to the task at hand." *Id.* 597. Fourth Circuit in *Sardis* reaffirmed *Daubert*, and sent a strong message to district courts to stop punting gatekeeping function on the theory that the opinions' deficiencies bear on the weight—and not the admissibility, holding,

> "When a party challenges an opposing expert's testimony as irrelevant, the court must satisfy itself that the proffered testimony is relevant to the issue at hand, for that is "a precondition to admissibility." *Daubert,* 509 U.S. at 592 []. And if that expert's proffered evidence is further alleged to be unreliable, then "the trial judge must determine whether the testimony has 'a reliable basis in the knowledge and experience of the relevant discipline.'" *Kumho Tire*, 526 U.S. at 149 (alteration omitted) (quoting *Daubert*, 509 U.S. at 592). While district courts have "broad discretion" in analyzing reliability, "such discretion does not include the decision 'to abandon the gatekeeping function.'" *Nease*, 848 F.3d at 230 (quoting *Kumho Tire*, 526 U.S. at 158–59 (Scalia, J., concurring)). "Rather, it is discretion to choose among reasonable means of excluding expertise that is *fausse* and science that is junky." *Kumho Tire*, 526 U.S. at 159 (Scalia, J., concurring)." *Sardis* 282.

Advisory Committee on Evidence Rules has also amended Fed.R.Evid.702 notes directing,

"[U]nfortunately many courts have held that the critical questions of the sufficiency of an expert's basis [for his testimony], and the application of the expert's methodology, are generally questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a) and are rejected by this amendment." *Sardis* 283.

"Where the admissibility of expert testimony is specifically questioned, Rule 702 and *Daubert* require that the district court make ***explicit findings***, whether by written opinion or orally on the record, as to the challenged preconditions to admissibility." *Sardis* 283. In the present case, "Just as in *Nease*, "[t]he court did not use *Daubert*'s guideposts or any other factors to assess the reliability of [Dr. Harris] testimony, and the court did not make any reliability findings." 848 F.3d at 230. Instead, it reflexively "[found] that [Plaintiff's objections] go to the weight [of the expert's] testimony, not [] admissibility." *Id.* at 230–31. By doing so, the court "abandoned its gatekeeping function," thereby abusing its discretion. *Id.* at 230." *Sardis* 282 (modified to reflect current case).

Further, the district court's error was ***harmful*** because the court relied on Harris testimony explicitly in granting the summary judgement alleging,

> "As Defendants' expert witness Dr. William S. Harris explained, in addition to being obvious over Morris and Anthony the benefits of consuming the claimed nutrients were well-known in the art as of 2010. This is reflected in an additional three combinations of references..." (Appx31)

The error was ***also harmful*** because Harris testimony created unfair prejudice against the Appellant, in that the district court explicitly and implicitly followed the Harris testimony in its opinion and decision granting summary judgment for the rejection of claims of the '847 Application, such as by the *same* mutilation of the disclosure and claims (Appx7352), *same* reconstruction of prior art to allege obviousness under §103 (Appx7359-7363), and *same* grounds of rejection under §101 citing same art "almonds," as suggested by Harris testimony not cited in USPTO examination (Appx7342-7349).

Had the district court faithfully executed its Fed.R.Evid.702 and *Daubert* responsibilities before granting the summary judgement, "[Fourth Circuit] precedent would have compelled it to exclude [Harris] experts' testimony." *Sardis* 279. And without the Harris testimony, the Appellees failed to meet their evidentiary burden on causes of action in this case including patentability. For example, without Harris testimony evidentiary support for medically complex issues such as "widely divergent conditions and diseases" (Appx21) and "well-known [in the art]" (Appx31) is absent. See *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 646 (4th.Cir.2018), ("all jurisdictions require expert testimony at least where the issues are medically complex and outside common knowledge and lay experience").

Therefore, the admission of Harris testimony was a harmful error that compromised Appellant's substantial rights. *Wickersham* 531. Therefore, this Court must reverse district court's admission of

Harris testimony.

IV. DUE PROCESS VIOLATION AND HARMFUL ERROR IN FAILURE TO CONSIDER FACTS AND CIRCUMSTANCES FOR RELIEF IN PENDING 2nd AMENDED COMPLAINT

A. Standard of Review

"Rule 15(a) declares that leave to amend 'shall be freely given when justice so requires'; this mandate is to be heeded. *See generally*, 3 Moore, Federal Practice (2d ed. 1948), §§ 15.08, 15.10. If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits." *Foman v. Davis*, 371 U.S. 178, 182 (1962). Also see *Johnson v. Oroweat Foods Co.,* 785 F.2d 503, 509 (4th.Cir.1986); *Pittston Co. v. U.S.,* 199 F.3d 694, 705 (4th.Cir.1999); *Edwards v. City of Goldsboro*; 178 F.3d 231, 240-243 (4th.Cir.1999).

B. District Court Disregarded Supreme Court Mandate to Enter *2nd Am. Complaint*

Appellant's motion for leave to file *2nd Am. Complaint* was filed on March 15, 2023 (Appx10908), for clarity and conformation to evidence on administrative record and crystallized during discovery and to new issues injected by Appellees in the motion for summary judgment on January 20, 2023. In an unlawful act, the district court first granted Appellees' motion for summary judgment on March 30, 2023, without considering the underlying facts and circumstances relied upon by the Appellant for proper relief in the *2nd Am. Complaint*, then the very next day on March 31, 2023, the district court denied the motion to file the

amended complaint without justifying reasons, under the pretext that the case is dismissed (Appx34).

The law is well settled, absent "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment," "leave to amend 'shall be freely given when justice so requires'; this mandate is to be heeded." *Foman* 182; *Pittston* 705; *Johnson* 509; *Edwards* 240-243. Delay alone is an insufficient reason to deny leave to amend. *Id.* Rather, the delay must be accompanied by prejudice, bad faith, or futility. *Id.*

There is no prejudice to the Appellees because the amendments sought here derive from matters already contained in some form in *1st Am. Complaint* (filed and automatically entered before the Appellees' filed their answer), evidence on administrative record and from discovery, and issues raised for the first time in motion for summary judgment filed on January 20, 2023, see table at Appx13901-13903. Further, the amendments merely clarify jurisdiction under 28 USC §1331 for adjudication of Plaintiff's constitutional rights to discoveries, due process, and just compensation for taking of her property and supplement facts to bad faith deprivation of patent rights, *already invoked in original complaint*. There is no alleged bad faith and no previously allowed amendments. Furthermore, *2nd Am. Complaint* would also not be futile. "Leave to amend . . . should only be denied on the ground of futility when the proposed amendment is clearly insufficient or frivolous on its face." *Johnson* 510.

Under similar circumstances as here, Fourth Circuit has reversed denial of amendments to complaint, requested about *17 months* after the original complaint was filed and after original complaint *had been dismissed*. *Edwards* 240-243; also *Pittston* 705; *Johnson* 509.

C. District Court Committed a Harmful Error in Denying the Entry of *2nd Am. Complaint* Violating Appellant's Right to Conform Complaint to Underlying Facts and Circumstances for Proper Relief on Merits

The denial of the entry of *2nd Am. Complaint* is clearly a ***harmful error*** because it denies the "opportunity to test [Plaintiff's] claim[s] on the merits" of specific "underlying facts [and] circumstances relied upon by a plaintiff may be a proper subject of relief" requested in the *2nd Am. Complaint* such as declaratory and injunctive relief to allow amendment of priority and pending claims considering new rejections raised in the motion for summary judgment, and to supplement facts from administrative record to bad faith deprivation of rights to discoveries (Appx13900-13910). It cannot be ignored. *Foman* 182.

The Appellees injected new issues into the civil action, during discovery such as in Harris testimony served on November 9, 2022 (e.g., priority issues) (Appx10957), and in the motion for summary judgement filed on January 20, 2023 (e.g., new prior art citations; Appx13901-13903). There were no 35 U.S.C. §101 rejections in examiners' and PTAB Decision (Appx6487-6488); although §101 was injected as a defense in Appellees' Answer filed on August 8, 2021, but without cited art and specific

claims implicated. Section 101 rejections over "almonds" and 103 rejections over *Debbouz, Rusing, Howard, Rath, Barker*, and *OIG Label Report* are new rejections vaguely raised during discovery (November-December 2022), but with particularity in the motion for summary judgement filed on January 20, 2023 (Appx8359-8370).

Thus, Appellees have injected new issues since the filing of 1st *Am. Complaint* in their motion for summary judgment. These points were noticed in the *2nd Am. Complaint* itself (Appx10953; Appx10957). Clearly, the Plaintiff has a right to amend the Complaint to conform to new issues injected by the Appellees including to request corresponding declaratory and injunctive relief such as to amend priority and pending claims due to newly raised grounds of rejection and art citation, in case instant claims are held unpatentable over those grounds or art. (Appx11022-11023). *Edwards* 243. "Entitlement to priority under §120 is a matter of law, and receives plenary review on appeal." *In re Daniels*, 144 F.3d 1452, 1455-56 (Fed.Cir.1998).

Further, Appellant has right to supplement facts in the Complaint from administrative record, to overcome the allegation that Complaint does not provide enough facts (Appx5).

The timing of filing amendments was outside Appellant's control. The *2nd Am. Complaint* was being drafted in November 2022 (Appx13895-13896) for clarity and conformation to further evidence but was delayed because new evidence and issues continually surfaced in discovery and motion for summary judgment and because higher litigation was burden placed on Appellant by the district court

(Section II.B supra).

It is a harmful error and manifest error of judgment on part of district court to deny entry of the *2nd Am. Complaint*, it amounts to district court taking leave of its senses. *Datascope* 828. Courts have mandated entry of such amendments. *Foman* 182; *Edwards* 240-243. This Court should reverse district court's denial of the entry of *2nd Am. Complaint*.

V. DUE PROCESS VIOLATIONS IN SUMMARY JUDGMENT GRANT WHILE PENDING INTERLOCUTORY APPEAL ON THE RECORD RIFE WITH DISPUTED FACTS, WHILE SUMMARY JUDGMENT FAILS AS A MATTER OF LAW

A. Standard of Review

Fourth Circuit undertakes plenary review of a district court's grant of summary judgment. *Lee v. Town of Seaboard*, 863 F.3d 323, 327 (4th.Cir.2017).

B. Summary Judgment is Unlawful Because Close of Discovery is Under Appeal, Appellees Expert is Objected, Claim Construction and Factual Issues Are Disputed

1. Close of Discovery is Under Appeal

The district court did not have authority to grant/enter summary judgment on March 30, 2023 (Appx19-33), because of pending interlocutory appeal filed on January 13, 2023 (Appx8326) from improper denial to enlarge discovery.

Fed.R.Civ.P.56(b) provides,

> "Unless a different time is set by local rule or the court orders otherwise, a party may file a motion for summary judgment at any time until 30 days after the close of all discovery."

Fed.R.Civ.P.56(d)(2) also "allows time [] to take discovery". This is also the interpretation of the US Supreme Court and added to the Notes of Advisory Committee, "*Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) ("In our view, the plain language of Rule 56(c) mandates the entry of summary judgment, *after* adequate time for discovery...)", 2010 Amendment. Also see *Harrods Ltd. v. Sixty Internet Domain Names*, 302 F.3d 214, 244 (4th.Cir.2002) holding "[S]ummary judgment prior to discovery can be particularly inappropriate when a case involves complex factual questions about intent and motive" which is the case here as the Appellant has alleged bad faith deprivation of rights to discoveries by Appellees. Hence, it is unambiguous that summary judgment must be entered *after* the close of discovery.

Further, Fourth Circuit has excused technical noncompliance with Rule 56(d), even in counseled cases, where the nonmoving party "has adequately informed the district court that the motion is premature and that more discovery is necessary." *Harrods* 244–45 ("nonmoving party's objections before the district court served as the functional equivalent of an affidavit" under Rule 56(d)) reversing grant of summary judgment under abuse of discretion standard. *Id.* 247. Accordingly, *Pro se*

Appellant had motioned the district court to strike the motion for summary judgment as premature and defective because of the need for additional discovery, including to identify witnesses for trial (Appx9858-9863; Appx9910-9914).

2. Appellees' Expert Testimony is Objected

Fed.R.Civ.P.56(c)(2) provides,

> "A party may object that the material cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence."

The Notes of Advisory Committee on Rules, 2010 Amendment, elucidate "the objection functions much as an objection at trial, adjusted for the pretrial setting." Accordingly, Appellant *objected* to Harris testimony in motion to disqualify Dr. Harris asserting testimony is *inadmissible* (Section III supra) and again in motion to strike or stay motion for summary judgment because the denial to exclude Harris testimony is under appeal (Appx9858-9863; Appx9910-9914). The Appellant specifically pointed out that the district court has acknowledged that 'the weight of the expert's [Dr. Harris'] testimony" is in question (Appx9861), and a district court's weighing the evidence at summary judgment is impermissible. *Tolan v. Cotton*, 134 S. Ct. 1861, 1866 (2014) (per curiam); *Jacobs v. N.C. Admin. Office of the Courts,* 780 F.3d 562, 568-569 (4th.Cir.2015).

Yet the district court explicitly and implicitly relied on Harris testimony in its opinion to grant the summary judgment even with respect to the question of patent eligibility (Section III.C supra). A court improperly weighs the evidence "[b]y failing to credit

evidence that contradict[s] some of its key factual conclusions." *Tolan* 1866.

3. Claim Construction and Related Facts Are Disputed

On legal determination of patent eligibility under 35 USC §101, the entry of summary judgment is unlawful before claim construction hearing, when *express disclaimer* "wherein [the intermixture of] omega-6 fatty acid(s) and antioxidant(s) [is] are not any single specific variety of a vegetable, a fruit, a nut, or a seed" (brackets indicate the variations) in *independent* claims 82, 99, and 115-116 is not given weight without explanation. The opinion on summary judgment grossly misinterprets the claims leaving out numerous limitations. See Section V.D.1 infra.

Further, both *1st* (¶¶25-27) and *2nd* (¶¶30-53) *Am. Complaints* assert proportional dosages of omega-6 fatty acids and antioxidants including polyphenols claimed in the '847 application is not well understood, routine, or purely conventional step in the prior art (Section V.C. and Table 3 infra), which is also asserted in Appellant's expert testimony (Appx7139-7163; Appx7196-7202; Appx7457-7536; Appx7585-7657) and opposition to summary judgment (Appx9912), while Harris testimony is objected to (discussed above).

Therefore, claim construction and related facts are disputed. "Whether claims [at issue] perform well-understood, routine, and conventional activities to a skilled artisan is a genuine issue of material fact making summary judgment inappropriate with respect to these claims." *Berkheimer v. HP Inc.*, 881

F.3d 1360, 1370 (Fed.Cir.2018).

Thus, entry of summary judgement is unlawful because of the foregoing reasons, which were submitted to the district court, but were not answered in the opinion (Appx19-32).

C. Summary Judgment is Unlawful Under Fed.R.Civ.P.56(a)Because Record is Rife with Disputed Facts

Fed.R.Civ.P.56(a) provides summary judgment is appropriate *only*,

> "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."

Appellant asserted in briefing to strike the motion to summary judgment,

> "pending claims [] expressly disclaim natural products such as almonds, and indisputably meet the requirements of 35 U.S.C. §101...The Amended Complaint (Dkt. 13 [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." (Appx9912)

Therefore, there is ***genuine dispute*** at least to ***two material facts***, (1) natural products (such as almonds) are expressly disclaimed in each of the *independent* claims 82, 99, 115, and 116, and

therefore in *all* claims, which refer to independent claims including 96-98 and 112; and (2) whether claimed proportional dosages of omega-6 fatty acids and antioxidants including polyphenols are well-understood, routine, and conventional activities, both of which have been ***repeatedly cited as disputed***, which are material facts affecting outcome of both eligibility under §101 and obviousness under §103. A disputed fact is material if it might affect the outcome of the suit. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

Appellant adequately opposed the motion for summary judgment in the briefing to strike the motion asserting the above disputed facts and that record is rife with further disputed facts citing *1st Am. Complaint* (¶¶6-8, 10, 25-28), Dr. Das' and Dr. Erickson's Expert Reports (Appx7139-7163; Appx7196-7202), Harris Report (Appx7309-7419), Dr. Das' Rebuttal to Harris Report (Appx7421-7546), Dr. Erickson' Rebuttal to Harris Report (Appx7548-7667), Excerpts from Harris Publications demonstrating relative dosages of omega-6 fatty acids and antioxidants including polyphenols remain poorly understood and long-felt unresolved need (Appx7669-7714), Institute of Medicine Report on DRIs confirming "lack of data on [omega-6] fatty acid requirement" (Appx8260-8262), Corrected Prior Art Tables vociferating massive reconstruction by Dr. Harris (Appx8264-8292), Reply in Support to Disqualify Dr. Harris (Appx8241-8256; Appx8297-8299). Each of the foregoing cited documents prominently disputes genuine issues of material facts, such that 70-90% of each document are directed to the disputed material facts. For example,

Das and Erickson Rebuttals dispute each of ¶¶19-224 in Harris Report (compare Appx7309-7419 with Appx7421-7546 and Appx7548-7667). Therefore, the district court did not need to search the documents for evidence, the evidence is ***glaringly visible***.

Celotex ruled summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Id.* 322-26. Even the absence of opposition to summary judgment itself does not warrant the entry of judgment in the movant's favor. *Custer v. Pan Am. Life Ins. Co.*, 12 F.4th 410, 415-16 (4th.Cir.1993).

Further, the evidence must be viewed in the light most favorable to the party opposing the motion, *Poller v. Columbia Broad. Sys., Inc.*, 368 U.S. 464, 473 (1962), with doubts resolved in favor of the nonmovant, *Cantor v. Detroit Edison Co.*, 428 U.S. 579, 582 (1976).

The district court failed to consider—let alone in the light most favorable to the Appellant—in its decision and opinion granting summary judgment the two genuine issues of disputed material facts discussed above, prominently cited in the pleadings, in the Appellant's expert report, and in the briefing to strike the summary judgment.

Because the record is replete with genuine dispute to many material facts, this Court must vacate the grant of summary judgment on patentability of claims as failing to meet the first

requirement of Fed.R.Civ.P.56(a).

D. Summary Judgment Ruling Fails Under Fed.R.Civ.P.56(a) as a Matter of Law on Patent Eligibility and Obviousness

1. Claims at Issue Are Patent Eligible as a Matter of Law

Whether a claim is directed to statutory subject matter under 35 USC §101 is a question of law reviewed *de novo*, without deference. *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352, 1355 (Fed.Cir.1999).

Claims Recite New Processes, Compositions, Manufacture, and Machine

During examination the Appellees agreed the terms "mixture"/"intermixture" will overcome §101 rejections (Appx3610) and withdrew the §101 rejection from claims at issue (Appx3622). See *In re Garnero*, 412 F.2d 276, 278-79 (CCPA 1969). Rather, claims 115-116 were substantially drafted by USPTO (Appx3635-3636). Accordingly, there is ***no §101 rejection in the PTAB decision*** (Appx6487-6488), it was improperly forced in this action.

35 USC §101 provides,

> "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."

Confirmed by ***no §102 novelty rejection*** against any claim at issue (Appx6487-6488),

- Independent claims 82 and 115 are patent

eligible as *new and useful manufacture and composition of matter*, as "packaged product" "intermixture"/"mixture";

- Independent claim 99 is patent eligible as *new and useful manufacture*, as "product" utilizing material where new process (§100(b)) yields daily tailored formulations based on diet cohorts;
- Claim 112, is patent eligible as *new and useful machine* "computer; system" utilizing new process (§100(b)) e.g., "remote user inputs" to facilitate the manufacture of *new and useful* product of claim 99; and
- Independent claim 116 is patent eligible as *new and useful process* of administering the formulations for new uses (§100(b)).

Claim Interpretation: Incontrovertible Disclaimer of Natural Products

"Because claim construction is a matter of law, the construction given the claims is reviewed *de novo* on appeal." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976-979, 989 (Fed.Cir.1995) (en banc).

Independent claim 82 includes the limitation, "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," and independent claims 99 and 115-116 include the limitation, "wherein omega-6 fatty acid(s) and antioxidant(s) are not any single specific variety of a vegetable, a fruit, a nut, or a seed." Therefore, *all* claims including 96-98 and 112 disclaim "a vegetable, a fruit, a nut, or a seed," including "almonds" cited in the opinion below (a nut and seed, Appx11574). This ***disclaimer is incontrovertible by law***, "[i]nventors

and applicants may intentionally disclaim, or disavow, subject matter that would otherwise fall within the scope of the claim." *Abbott Laboratories v. Sandoz, Inc.*, 566 F.3d 1282, 1288 (Fed.Cir.2009). "[t]he inventor's intention, as expressed in the specification, is regarded as dispositive." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed.Cir.2005).

The '847 Patent Application is a legal instrument, which makes it illegal to interpret the claims outside the express limitations in the claims, requiring "***the scope of the present invention is defined by the appended claims***" (Appx354). *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388 (1996). It is a ***legal error*** to excise limitations from the claims including the disclaimer, and to interject arbitrary interpretation into the claims contradicting the terms of the claims. *Markman* 52 F.3d 967, 980.

Because claims are not drawn to laws of nature, natural phenomena, and abstract ideas, ***§101 inquiry is over at step one*** of *Alice Corp. Pty. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014); *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 132 S.Ct. 1289, 1296-97 (2012). Appellants claims explicitly disclaim "a vegetable, a fruit, a nut, or a seed [almonds]," therefore ***do not tie up*** the use of the allegedly underlying naturally existing subject matter.

Claim Interpretation: Proportional Dosages of Omega-6 and Antioxidants, and Remote User Inputs, and Specific Uses

In *Mayo* at 1298 the Supreme Court emphasized the importance of considering claims as a whole as part of the eligibility analysis; *also Alice* 2355 n.3 (quoting *Diehr* 188). Violating the Supreme Court

precedent, district court ***left out numerous limitations*** from independent claims besides the disclaimer, including:

> Claim 82: "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";
> Claim 99: "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";
> Claim 112: "wherein the program operates in response to remote user inputs of dietary cohorts and/or preferences"; and
> Claim 115-116: "from 1 to 40 g dosage of omega-6 fatty acid(s)... from 25 to 10 g dosage of antioxidant(s)...the dosage of ***antioxidants includes*** at least 5 mg of phytochemical(s)" and "medical conditions or diseases [specified]".

Notably dosage—by definition—means restriction (Appx7451; Appx7579), and each of the claims, the specification, and the prosecution history comport with claims being drawn to proportional dosages (restricted) of omega-6 and antioxidants including polyphenols (Appx7486-7487; Appx7527; Appx7614-7615; Appx7651). "To ascertain the meaning of claims, we consider three sources: The claims, the specification, and the prosecution history." *Markman* 979.

Appellees' ***professional opinion*** confirms that claimed inventions as a whole are ***not*** "well understood, routine, or conventional activity' previously known to the industry," because there is no §102 rejection against the claims at issue. Likewise, the district court opinion fails to explain based on what expert opinion it finds the claims as a whole to be "well-known, routine, and conventional activity." *Lipitor* 646. On the contrary, the '847 application and Appellant's expert testimony demonstrate claims as a whole are not well-understood. (Section V.C. supra, Table 3 infra). Therefore, the claims transform (though unnecessary) any alleged ineligible subject matter, and step two of §101 inquiry is also met. *Alice* 2359-2360.

For all the foregoing reasons, this court must reverse district court's ***legally erroneous*** ineligibility decision under 35 USC §101.

2. Claim 112 is Not Held Obvious and Claims 82, 99, 115-116 and Dependent Claims Are Not Obvious as a Matter of Law

"Obviousness [including on summary judgment], 35 U.S.C. §103, is reviewed as a legal conclusion [subject to our full and independent review] based upon underlying facts of four general categories, *viz.* the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill at the time the invention was made, and any objective considerations that may be present. *Graham v. John Deere Co.*, 383 U.S. 1, 17 [] (1966)." *Continental Can Co. USA, v. Monsanto Co.*,

948 F.2d 1264, 1270 (Fed.Cir.1991).

District court finds claim 112 to be patentable under §103 (Appx29-31). Further, the facts indisputably lead to legal conclusion of non-obviousness of independent claims 82, 99, and 115-116, as discussed below.

This Court Must First Excise Erroneously Admitted Harris Testimony

This Court must first excise Harris testimony that was erroneously admitted (Section III.C. supra), because "[i]nadmissible evidence contributes nothing to a 'legally sufficient evidentiary basis.'" *Weisgram v. Marley Co.,* 528 U.S. 440, 453–56 (2000).

No Suggestion in Prior Art to Combine Elements as Claimed

Each of claims 82, 99, and 115-116, include the limitations or variation thereof in [],

> "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...," and

wherein claims 82 and 99 are product claims ***comprising labeling/tailoring processes*** and claim 116 is directed to ***new uses***. Specification explains restricted and proportional requirements of omega-6 and antioxidants including polyphenols/phytochemicals are not well-understood,

they should be preformulated to keep consumers in "optimal/safe range," and tailored based on cohorts for prevention/treatment. (Appx349-355, Appx358-359, Appx369-373, Appx394-395).

Motion and reply (Appx9861; Appx9911-9912) to strike/oppose motion for summary judgment ***expressly directed*** the court to following documents on record evidencing poorly understood factors, although the court should consider entire record, including PTAB appeal (e.g., Appx4744-4752; Appx4767) and *2nd Am. Complaint* (Appx10923-10984). *Celotex* 322-26.

Table 3	
Document	**Teaching/Suggestion**
Lands WE, Ann. N.Y.Acad.Sci. 1055: 179–192(2005) (*1st Am. Compl.*, Appx305¶25 (Appx4773-4786))	<0.5% of calories from n-6 linoleic acid (<*1g/day* for 1800 calorie diet) (Appx4777). No suggestion on dosage of total antioxidants including polyphenols.
US 2008/0213239A1 ("Morris") (*1st Am. Compl.* Appx305-307 ¶¶25-27, (Appx9401-9424))	Omega-6 is not essential and replaceable with omeg-3; no or zero omega-6 in formulations 1-6; and 0.070g in formulations 7-27 (70mg GLA). 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). (Appx8264-8271)
US 2007/0166411A1 ("Anthony") (*1st Am.Compl.*, Appx306 ¶¶25-26 (Appx9426-9439))	Defines linoleic acid as omega-3 and α-linolenic acid as omega-6 (¶49, ¶51) and its exemplary formulations in Tables 2 and 7 comprise 0.2-0.4g α-linolenic acid [omega-6]. No suggestion on dosage of total antioxidants including polyphenols. (Appx8264-8271)
Niki, "Lipid peroxidation: Physiological levels and dual biological effects" Free.Radic.Biol Med.2009 Sepl:47(5):469-84. (*1st Am.Compl.*, Appx306 ¶26 (Appx4834-4845))	Antioxidants are randomly recommended in prior art without teaching dosages and context. (Appx4844-4845)
Mennen, "Risks and safety of polyphenol consumption" Am.J.Clin Nutr.2005;81(suppl):326S–9S (*1st Am.Compl.*, Appx306 ¶27 (Appx4787-4789))	Dosage of polyphenols is not well understood, routine, or purely conventional step in the prior art. No mention of dosage of omega-6 and antioxidants.

Appellant's Experts Drs. Das and Erickson Testimonies (Appx7129-7163; Appx7188-7203; Appx7421-7546; Appx7548-7667).	Total dosage of omega-6 fatty acids and total antioxidants including polyphenols are poorly understood. '847 application demonstrates unexpected results and solves long-felt critical unmet need.
Dietary Guidelines for Americans, U.S.DHHS (Appellant's Expert Testimonies (Appx7470; Appx7522; Appx7598; Appx7647))	No suggestion on total omega-6 fatty acids and total antioxidants including polyphenols.
Harrison's Principles of Internal Medicine, 20th Edition (2018) (Appellant's Expert Testimony (Appx7437))	No suggestion on total omega-6 fatty acids and total antioxidants including polyphenols, while teaching the use of medications to modulate the effect of prostaglandins, omega-6 metabolites.
University of California, Division of Agriculture and Natural Resources (2008) (Appellant's Expert Testimonies (Appx7470; Appx7598))	Confirms dosages of phytochemicals including polyphenols are not well-understood (Appx12023-12026).
Excerpts to Dr. Harris' Publications (Appx7669-7714) and Appellant's Expert Testimonies (Appx7462-7466; Appx7590-7594))	Admitting requirements for omega-6 fatty acids and antioxidants are poorly understood.
Institute of Medicine 2005 Dietary Reference Intake	Because of the lack of data on the n-6

(Appellant's Expert Testimonies (Appx7520-7521; Appx7646-7647))	fatty acid requirement in healthy individuals, an EAR cannot be set based on correction of a deficiency. (Appx8260-8262). No suggestion on dosage of total antioxidants including polyphenols.
Randomly sold products comprising omega-6 fatty acids, antioxidants, and polyphenols (*1st Am.Compl.*, Appx301-307 ¶¶ 6, 10, 30 (Appellant's Expert Testimonies (Appx7131-7142; Appx7161-7163; Appx7197; Appx7201; Appx7467-7471; Appx7478; Appx7533; Appx7595-7599; Appx7606))	No suggestion on dosage of total omega-6 fatty acids and total antioxidants including polyphenols
Tables delineating detailed differences between instant claims 82 and 99 and cited art: M*orris+Anthony+Howard*, *Debbouz+OIG*, and *Rusing+OIG* (Appx8264-8292) and (Appellant's Expert Testimonies (Appx7478-7513; Appx7607-7640)	Different problems to be solved; and no suggestion on total omega-6 fatty acids and total antioxidants including polyphenols.

Thus, the prior art as a whole, including *Morris* and *Anthony*, fails to recognize let alone solve, the problem of proportional dosages of total omega-6 fatty acids and total antioxidants including polyphenols/phytochemicals. The court alleges "three combinations of references" allegedly "disclose the claimed omega-6 fatty acid, antioxidant, and

polyphenol dosages" but fails to mention which references and pincite the disclosures (Appx31). To the extent the reference is to M*orris+Anthony+Howard*, *Debbouz+OIG*, and *Rusing+OIG*, these references do not provide any teaching on total proportional dosages of omega-6 fatty acids and antioxidants including polyphenols, taken alone or in combination (see Table 3).

There must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor. *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 665 (Fed.Cir.2000). "Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention." *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546 (Fed.Cir.1998).

No Overlapping Ranges, Teaching Away, and Unexpected Results

Morris does not teach overlapping ranges because there is no suggestion of dosage of polyphenols in *Morris* (Appx9412; Appx8267). Further, "The presumption [of obviousness] can be rebutted if it can be shown that the prior art teaches away from the claimed range, ***or*** the claimed range produces new and unexpected results." *Ormco Corp. v. Align Technology, Inc.*, 463 F.3d 1299, 1311 (Fed.Cir.2006). Both foregoing factors hold true here:

(1) *Morris* teaches omega-6 is optional (¶46),

formulations 1-6 contain no or zero omega-6 and formulations 7-27 contain 0.070g omega-6 (70mg GLA), and teaches unlimited antioxidants, e.g., above 31g (Appx7149; Appx7199). Thus, *Morris* teaches away from lower limit of 1g omega-6 and upper limit of 10g antioxidants dosage, and "***too frequently***" (Appx7609-7613). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference [] would be led in a direction divergent from the path that was taken by the applicant." *Ormco* 1308.

(2) Appellant has demonstrated unexpected results as testified by expert testimonies. "USPA '847 Examples 6, 8, 9, 10, 12, and 14, teach at least 11g/day omega-6 dosage was required to overcome adverse health. In other words, Morris' 210 mg/day [if taken 3x/day] GLA formulations will not be able to meet the 11g or higher needs of omega-6 of some individuals. This is an unexpected result in comparison to Morris and prior art as a whole. USPA '847 teaches in Example 8 that low intake of fatty acids and high intake of antioxidants including polyphenols resulted in neural disease in the subjects. Example 13 similarly show low intake of omega 6 fatty aid and high intake of antioxidants associated with neural disease. These are unexpected results with respect to antioxidants." (Appx7152).

Secondary Considerations Confirm the Claimed Inventions Were Not Obvious

"[s]econdary considerations [long felt but unsolved needs, failure of others] which, when present, must be considered. [] It does not appear that that was done." *Loctite Corp. v. Ultraseal Ltd.,* 781 F.2d 861, 873 (Fed.Cir.1985).

Appellant has provided abundant evidence of long felt but unsolved needs and failure of others (Appx7131-7132; Appx7153-7158; Appx7202; Appx7522-7536; Appx7648-7657) including,

> "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." (Appx7657).

The district court ignored those vital facts of non-obviousness despite *Graham* and *Loctite*.

3. Rights to Further Arguments Reserved

Further patentability discussion, including on dependent claims, is not possible here because of word limitation and denial of brief enlargement to properly argue the number of issues (ECF.No.16). This Court is referred to further arguments and evidence on patentability on record including the *2nd Am. Complaint* (Appx10923-10984). Rights to further arguments are reserved, disregarding the right would result in an unfair procedure. *Advanced Magnetic Closures v. Rome Fastener*, 607 F.3d 817, 833 (Fed.Cir.2010).

CLAIMS AT ISSUE IN USPA 13/877,847

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.

83. The product according to claim 82, wherein:
- the omega-6 fatty acids comprise one or more fatty acids selected from the group consisting of linoleic (C18:2), conjugated-linoleic (C18:2), gamma-linolenic (C18:3), eicosadienoic (C20:2), di-homo-gamma-linolenic (C20:3), and arachidonic (C20:4), and/or
- the antioxidants are 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 (CoQ10), glutathione and vitamin E.

84. The product according to claim 82, wherein the one or more polyphenols is selected from the group consisting of flavonoids, phenolic acids, lignans,

provide unbiased judges. Recusal is required when, objectively speaking, the probability of actual bias on the part of the judge or decisionmaker is too high to be constitutionally tolerable. *Aetna Life Ins. Co. v. LaVoie*, 475 U.S. 813, 825 (1986).

CONCLUSION AND RELEIF SOUGHT

Review establishes that the judgment was premised on "parade of legal errors" cited above. Decisions based on such fundamental legal errors cannot stand. *Jones v. Hardy*, 727 F.2d 1524, 1527 (Fed.Cir.1984). Reversal of each of the decisions at issue (Appx1-34 and Appx13998-13999) is required, except for decision to grant extension to disclose expert rebuttals (Appx13). This Court must direct the district court to enter judgment as a matter of law in Appellant's favor on patentability of all claims at issue, remand the case for further proceedings as to non-patent counts, order costs on the civil action and this appeal in favor of Appellant, and consider just and suitable relief for district court's failure to provide unbiased judges.

Urvashi Bhagat, Pro se Appellant

ADDENDUM

A. Opinions and Orders at Issue Court are included supra at App.37a-66a.
B. Pending Claims included infra at App.153a-169a.
C. The '847 Application is included in Supplemental Appendix (Appx347-416)

4. Reversal of District Court Decision is Required

The record here provides abundant facts essential to formulating a conclusion of patentability of claims 82, 99, 112, and 115-116, and the dependent claims, requiring this Court to reverse district court's unpatentability decision (Appx19-33). *Gardner v. TEC Systems*, 725 F.2d 1338, 1344 (Fed.Cir.1984).

E. 2nd Reason to Enter Judgment as a Matter of Law in Appellant's Favor on Patentability per *Weisgram* Standard

The inadmissibility of Harris testimony (Section III. supra), and the equitable considerations of fairness to both parties counsel this Court to direct the district court to enter patentability judgment as a matter of law in Appellant's favor. One of the "key[s] to [our] exercise of . . . discretion" in this analysis is "fairness to the parties." *Weisgram*, 528 U.S. at 454.

"Writing for the unanimous *Weisgram* Court, Justice Ginsburg observed that '[s]ince *Daubert*, . . . parties relying on expert evidence have had notice of the exacting standards of reliability such evidence must meet.' *Id.* at 455...So it is fair to enter judgment as a matter of law for the losing party below when the appellate court finds the prevailing party's expert testimony inadmissible on appeal, because "[i]t is implausible to suggest, post-*Daubert*, that parties will initially present less than their best expert evidence in the expectation of a second chance should their first try fail." *Id.* at 455–56...That fairness is only amplified in a case like this, where '[the Appellees were] on notice every step of the way that [Appellant] was challenging [their] expert[], [and

they] made no attempt to add or substitute other evidence.' *Id.* at 456." *Sardis* 299. As in *Weisgram*, the Appellees have held that the evidence presented below was sufficient to support the judgment entered in their favor (Appx9881).

Given similar circumstances of this case and that in *Weisgram*, this Court should follow the path already cleared by the Supreme Court, and direct that judgment as a matter of law be entered in Appellant's favor holding instant claims patentable.

VI. DUE PROCESS VIOLATIONS IN FAILING TO PROVIDE UNBIASED JUDGES

The district court failed to provide due process and fair proceedings in accordance with Fifth Amendment and *Snyder*. The court's opinions and orders encompass the following legal errors: (1) non-consideration of invocation of jurisdiction under 28 USC §1331; (2) non-consideration of Appellant's express statements in pleadings; (3) non-consideration of Fed.R.Civ.P.83; (4) non-consideration of *Daubert* standards for admissibility; (5) non-consideration of *Foman* mandate for complaint amendment; (6) non-consideration of the invention as claimed; (7) absence of the factual findings on the four inquiries mandated by *Graham*; (8) application of improper overlap test under 35 U.S.C. §103; and (9) non-consideration of objective indicia of non-obviousness. Further, the court silenced the Appellant in hearing (Appx9922-9948) and pressed her to withdraw the action (Appx9932). The foregoing and every ruling substantially against the Appellant (Table 2 supra) demonstrate failure to

stilbenes, punicalagins, hydroxycinnamic acids, and tyrosols.

85. The product according to claim 82, wherein the antioxidants comprise one or more phytosterols selected from the group consisting of campesterol, sitosterol, gamma sitosterol, and stigmasterol.

86. The product according to claim 82, wherein the antioxidants comprise one or more phytosterols, wherein the dosage of the one or more phytosterols is greater than 150mg.

87. The product according to claim 82, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements collectively comprise phytochemicals, lipids, antioxidants, vitamins, minerals, probiotics, prebiotics, microorganisms, and fiber.

88. A method of using the product according to claim 82, the method comprising:

administering the dosage to an individual, wherein the individual belongs to a diet cohort selected from the group consisting of one or more of the following:

(i) a diet cohort based on primary dietary ingredients of the individual's daily or weekly diet which is determined by comparing levels of one or more of antioxidants, phytochemicals, vitamins, minerals, lipids, carbohydrates, and proteins from foods of the individual's diet with levels in a set of predetermined cohorts;

(ii) a diet cohort based on average daily consumption of one or more of grains, vegetables, fruits, legumes, dairy, meats, seafood, herbs, sweeteners, and beverages;
(iii) a diet cohort which is predominantly vegetable-based, meat-based or seafood-based; or
(iv) a diet cohort based on gender, age, genetic profile, family history, climactic temperature, or medical condition.

89. The product according to claim 82, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements collectively comprise omega-9 fatty acids in an amount less than 60% by weight of total lipids.

91. The product according to claim 82, wherein at least one of the one or more formulations are in the form of a liquid, powder, topical cream, or patch.

92. The product according to claim 82, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements collectively comprise one or more of the following:
(i) omega-3 fatty acids, wherein the omega-6 fatty acids to omega-3 fatty acids ratio is 1:1 to 50:1;
(ii) omega-9 fatty acids, wherein the omega-9 fatty acids to omega-6 fatty acids ratio is less than 4:1;
(iii) monounsaturated and polyunsaturated fatty acids, and wherein the monounsaturated to polyunsaturated fatty acids ratio is less than 4:1;

(iv) omega-3 fatty acids, wherein the amount of omega-3 fatty acids is less than 20% by weight of total lipids;
(v) the dosage of omega-6 fatty acids is less than 30g; or
(vi) omega-3 fatty acids, wherein the dosage of the omega-3 fatty acids is less than 2g.

93. The product according to claim 82, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements collectively comprise:

- folate in dosage 100-1000 mcg; and/or
- one or more phytosterols in dosage 150-1000 mg; and/or
- one or more carotenoids in dosage 100-14,000 mcg; and/or
- betaine and/or choline in dosage 25-600 mg; and/or
- Se in dosage 10-135 mcg; and/or
- one or more fibers in dosage 5-50g; and/or
- Vitamin E-alpha/gamma in dosage 0.01-0.30% by weight of total lipids.

94. The product according to claim 82, comprising a plurality of formulations, food items and/or supplements wherein one formulation, food item and/or supplement thereof provides:

(i) one or more polyphenols in a dosage less than 5 mg, but collectively the formulations provide greater than 5mg of polyphenols; and/or
(ii) antioxidants in a dosage less than 25mg, but collectively the formulations provide from 25mg to 10g of antioxidants; and/or

(iii) omega-6 fatty acids in a dosage less than 1g, but collectively the formulations provide from 1 to 40g of omega-6 fatty acids.

95. The product according to claim 82, comprising a kit comprising plurality of the one or more formulations, food items, and/or supplements, wherein:

(i) the kit comprises formulation(s) which collectively provide an amount of nutrients from 0.0001 to 100 g/kg body weight; and/or

(ii) the kit comprises from 2-20 formulations for daily consumption by the individual, collectively comprising 40-80% of individual's daily calories; and/or

(iii) the kit comprises 10-50% calories from protein, 15-50% calories from lipids, and 35-85% calories from carbohydrates; and/or

(iv) the kit comprises 2-20 formulations for daily consumption by the individual, which collectively deliver at least 50% of daily micronutrients for the individual, and/or

(v) the kit comprises at least one of: vegetable or vegetable juice packs, fruit or fruit juice packs, dry grain packs, cereal packs, legume, grain, nuts, or seeds packs, meat or seafood packs, or herbs, lipids, meals, snack, side dish, salad, desserts, milks, powder, puree, or yogurt packs.

96. The method according to claim 97, wherein the dosage is administered to aid acid-base balance in the individual.

97. A method of prophylaxis and/or treatment of a medical condition or disease in the individual, the method comprising:

administering a dosage of the product according to claim 82 to the individual.

98. The method according to claim 97, wherein the medical condition or disease is selected from the group consisting of menopause, aging, allergy, musculoskeletal disorders, vascular diseases, hypercholesterolemia, mood swing, reduced cognitive function, cancer, neural disorders, mental disorders, renal diseases, endocrine disorders, thyroid disturbances, weight gain, obesity, diabetes, digestive system disorders, reproductive disorders, infant abnormalities, pulmonary disorders, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, autoimmune diseases, infectious diseases, and inflammatory diseases.

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 of

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.

100. The method according to claim 99, wherein:
- the antioxidants include one or more polyphenols selected from the group consisting of flavonoids, flavones, isoflavones, catechins, anthocyanidins, phenolic acids, lignans, stilbenes, punicalagins, hydroxycinnamic acids, and tyrosols; and/or
- the omega-6 fatty acids comprise one or more fatty acids selected from the group consisting of linoleic (C18:2), conjugated-linoleic (C18:2), gamma-linolenic (C18:3), eicosadienoic (C20:2), di-homo-gamma-linolenic (C20:3), and arachidonic (C20:4), and/or
- the antioxidant(s) further comprise one or more compounds selected from the group consisting of isothiocyanates, carotenoids, allyl sulfides, terpenes, limonoids, phytosterols, ascorbic acid (vitamin C), folic acid, Se, superoxide dismutase (SOD), catalase, glutathione peroxidase (GSHpx), coenzyme Q10 (CoQ10), glutathione and vitamin E.

101. The method according to claim 99, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements collectively comprise phytochemicals, lipids, antioxidants, vitamins, minerals, probiotics, prebiotics, microorganisms, and fiber.

102. The method according to claim 99, wherein the individual belongs to a diet cohort selected from one or more of the following:

(i) a diet cohort based on primary dietary ingredients of the individual's daily or weekly diet which is determined by comparing levels of one or more of antioxidants, phytochemicals, vitamins, minerals, lipids, carbohydrates, and proteins from foods of the individual's diet with levels in a set of predetermined cohorts;

(ii) a diet cohort based on average daily consumption of one or more of grains, vegetables, fruits, legumes, dairy, meats, seafood, herbs, sweeteners, and beverages;

(iii) a diet cohort which is predominantly vegetable-based, meat-based or seafood-based; or

(iv) a diet cohort based on gender, age, genetic profile, family history, climactic temperature, or medical condition.

103. The method according to claim 99, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements provide one or more of:

(i) micronutrients to supplement the individual's diet;

(ii) less than 500 calories or less than 25% of daily calories; or

(iii) lipids from natural sources to supplement the individual's diet, wherein the natural sources include oils, butters, margarines, nuts, and seeds.

104. The method according to claim 99, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements provide one or more of:

(i) supplement, balance, or replace the individual's daily food consumption based on the individual's diet cohort;
(ii) at least 25% of daily or weekly total caloric intake for the individual; or
(iii) satiety and diet dietary preference of the individual.

107. The method according to claim 99, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements collectively comprise one or more of the following:

(i) omega-3 fatty acids, wherein the omega-6 fatty acids to omega-3 fatty acids ratio is 1:1 to 50:1;
(ii) omega-9 fatty acids, wherein the omega-9 fatty acids to omega-6 fatty acids ratio is less than 6:1:
(iii) monounsaturated and polyunsaturated fatty acids, wherein the monounsaturated to polyunsaturated fatty acids ratio is less than 6:1;
(v) omega-9 fatty acids, wherein the amount of omega-9 fatty acids is less than 60% by weight of total lipids;
(vi) the amount of omega-6 fatty acids is greater than 20% by weight of total lipids
(vii) comprise omega-3 fatty acids, wherein the amount of omega-3 fatty acids is less than 20% by weight of total lipids;

(viii) the dosage of omega-6 fatty acids is less than 35g; or
(ix) omega-3 fatty acids, wherein dosage of the omega-3 fatty acids is less than 2g.

108. The method according to claim 99, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements comprise:
(i) one or more polyphenols in dosage less than 300mg; and/or
(ii) folate in dosage less than 1000mcg; and/or
(iii) one or more phytosterols in dosage less than 1000mg; and/or
(iv) one or more carotenoids in dosage less than 14,000mcg; and/or
(v) betaine and/or choline in dosage less than 600mg; and/or
(vi) Se in dosage less than 135mcg; and/or
(vii) one or more fibers in dosage less than 50g; and/or
(viii) Vitamin E-alpha/gamma in dosage 0.01-0.30% by weight of total lipids.

109. The method according to claim 99, wherein a packaged kit comprises the one or more formulations, food items, and/or supplements, wherein a label is attached to the packaging of the kit, wherein one or more of the following apply:
(i) the kit comprises individual portions of food items for daily consumption;
(ii) the kit comprises individual portions of food items for supplementation of daily diet of the individual;

(iii) the kit comprises a label comprising at least one indication of the suitability of the formulations or packages for a consumer with a specific dietary profile or cohort;
(iv) the kit comprises an indication of the upper limit of average daily consumption of items in the kit; or
(v) the kit comprises at least one of: vegetable or vegetable juice packs, fruit or fruit juice packs, dry grain packs, cereal packs, legume, grain, nuts, or seeds packs, meat or seafood packs, or herbs, lipids, meals, snack, side dish, salad, desserts, milks, powder, puree, or yogurt packs.

110. The method according to claim 99, wherein a list is prepared for the individual, which provides:
(i) predetermined natural sources of lipids, the sources selected from oils, butters, margarines, nuts and seeds, and optionally one or more of nutrients selected from antioxidants, phytochemicals, vitamins and minerals in amounts that optimizes dietary nutrients such that the individual's lipid intake provides a beneficial effect to the individual; and/or
(ii) a recommended consumption of food items over at least one week; and/or
(iii) food items that should not be included in the individual's daily diet; food items that should be limited in the individual's daily diet; or food items that should be added to the individual's daily diet.

112. A computer system configured to computationally implement a method according to claim 99, comprising:

(a) a computing device having a memory;
(b) an input device for entering information regarding the individual's dietary preferences into the memory;
(c) a database in the memory for storing the information;
(d) a first program module, for execution in the computing device, for determining a dietary cohort of the individual corresponding to the individual's dietary preferences, wherein the program operates in response to remote user inputs of dietary cohorts and/or preferences; wherein the dietary cohort of the individual is
    (i) predetermined and entered directly in the computing device; and/or
    (ii) determined either manually or computationally in response to remote user inputs of dietary preferences via a web connection; and/or
    (iii) selected from predominantly vegetable-based, seafood based and meat based;
(e) a nutrient database for storing dietary guidelines relative to dietary cohorts of an individual; wherein optionally the nutrient database comprises suitable ranges for average daily dietary consumption of nutrients corresponding to each dietary cohort, and/or suitable ranges for daily dietary consumption of carbohydrates, protein, vitamins, minerals and phytochemicals;
(f) a knowledge database having rules for manipulating the information in the database to provide a recommended future nutrition program for the individual, the nutrition program comprising one or more of nutrients selected from antioxidants, phytochemicals, lipids, vitamins and minerals in

amounts that provide a beneficial effect to the individual, wherein a suitable daily dosage of omega-6 fatty acids and antioxidants including polyphenols is included in the program;

(g) a second program module, for execution in the computing device, for applying the rules in the knowledge database to the information in the database and to the guidelines in the nutrient database and for generating a nutrition program for the individual in a result database; and

(h) means for outputting the contents of the result database, under the direction of the second program module,

wherein the nutrition program comprises a listing of formulations, optionally comprising food items, wherein from 1 to 40g of omega-6 fatty acids and from 25mg to 10g of antioxidants comprising at least 5mg of one or more polyphenols are included in the program for daily consumption by the individual.

113. The product according to claim 82, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements comprise one or more of

(i) omega-3 fatty acids, wherein the omega-6 fatty acids to omega-3 fatty acids ratio is from 6:1 to 25:1;

(ii) omega-9 fatty acids, wherein the omega-9 fatty acids to omega-6 fatty acids ratio is less than 2:1;

(iii) monounsaturated and polyunsaturated fatty acids, wherein the monounsaturated to polyunsaturated fatty acids ratio is less than 2:1;

(iv) omega-9 fatty acids, wherein the amount of omega-9 fatty acids is less than 40% by weight of total lipids;
(v) omega-6 fatty acids in an amount greater than 35% by weight of total lipids;
(vi) omega 3 fatty acids, in an amount less than 10% by weight of total lipids;
(vii) omega-6 fatty acids in a dosage less than 20g; or
(viii) omega-3 fatty acids in a dosage less than 1g.

114. The product according to claim 82, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements comprise:
(i) one or more polyphenols in a dosage less than 140mg; and/or
(ii) folate in dosage less than 400 mcg; and/or
(iii) one or more phytosterols in dosage less than 550 mg; and/or
(iv) one or more carotenoids in dosage less than 3,000 mcg; and/or
(v) betaine and/or choline in dosage less than 200 mg; and/or
(vi) Se in dosage less than 35 mcg; and/or
(vii) one or more fibers in dosage less than 20g; and/or
(viii) Vitamin E-alpha/gamma in dosage 0.01-0.05% by weight of total lipids.

115. A nutritional formulation comprising a mixture of:

(a) from 1 to 40 g dosage of omega-6 fatty acid(s) selected from the group consisting of linoleic (C18:2), conjugated-linoleic (C18:2), gamma-linolenic (C18:3),

eicosadienoic (C20:2), di-homo-gamma-linolenic (C20:3), and arachidonic (C20:4); and

(b) from 25 to 10 g dosage of antioxidant(s) selected from the group consisting of ascorbic acid (vitamin C), folic acid (folate), selenium, copper, zinc, superoxide dismutase (SOD), catalase, glutathione peroxidase (GSHpx), coenzyme Q10 (CoQ10), glutathione, vitamin A, vitamin E, and vitamin D; wherein

(c) the dosage of antioxidants includes at least 5 mg of phytochemical(s) selected from the group consisting of monophenols, polyphenols, phenolic acids, hydroxycinnamic acids, tyrosols, carotenoids, monoterpenes, saponins, phytosterols, triterpenoids, betalains, organosulfides, indoles, glucosinolates, and sulfur compounds;

wherein the omega-6 fatty acid(s) and antioxidant(s) is not any single specific variety of a vegetable, a fruit, a nut, or a seed.

116. A method for treating medical conditions or diseases selected from the group consisting of menopause, aging, allergy, musculoskeletal disorders, vascular diseases, hypercholesterolemia, mood swing, reduced cognitive function, cancer, neural disorders, mental disorders, renal diseases, endocrine disorders, thyroid disturbances, weight gain, obesity, diabetes, digestive system disorders, reproductive disorders, infant abnormalities, pulmonary disorders, ophthalmologic disorders, dermatological disorders, sleep disorders, dental diseases, autoimmune diseases, infectious diseases, and inflammatory diseases, the method comprising:

administering to a subject the nutritional formulation in a dosage sufficient to treat the medical condition or disease wherein the nutritional formulation comprises:

(a) from 1 to 40 g dosage of omega-6 fatty acid(s) selected from the group consisting of linoleic (C18:2), conjugated-linoleic (C18:2), gamma-linolenic (C18:3), eicosadienoic (C20:2), di-homo-gamma-linolenic (C20:3), and arachidonic (C20:4); and

(b) from 25 to 10g dosage of antioxidant(s) selected from the group consisting of ascorbic acid (vitamin C), folic acid (folate), selenium, copper, zinc, superoxide dismutase (SOD), catalase, glutathione peroxidase (GSHpx), coenzyme Q10 (CoQ10), glutathione, vitamin A, vitamin E, and vitamin D; wherein

(c) the dosage of antioxidants includes at least 5 mg of phytochemical(s) selected from the group consisting of monophenols, polyphenols, phenolic acids, hydroxycinnamic acids, tyrosols, carotenoids, monoterpenes, saponins, phytosterols, triterpenoids, betalains, organosulfides, indoles, glucosinolates, and sulfur compounds;

wherein the omega-6 fatty acid(s) and antioxidant(s) is not any single specific variety of a vegetable, a fruit, a nut, or a seed.

117. The product according to claim 82, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements collectively comprise phytochemicals selected from the group consisting of monophenols, phenolic acids, hydroxycinnamic acids, tyrosols, monoterpenes,

saponins, triterpenoids, betalains, organosulfides, indoles, glucosinolates, and sulfur compounds.

118. The method according to claim 99, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements collectively comprise phytochemicals selected from the group consisting of monophenols, phenolic acids, hydroxycinnamic acids, tyrosols, monoterpenes, saponins, triterpenoids, betalains, organosulfides, indoles, glucosinolates, and sulfur compounds.

119. The product according to claim 82, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements collectively comprise omega-6 fatty acids in an amount greater than 20% by weight of total lipids.

120. The product according to claim 82, wherein the nutritional formulation(s) comprise(s) one or more food items and/or supplements, wherein the one or more formulations, food items, and/or supplements collectively comprise one or more polyphenols in dosage less than 300mg.

Case No. 2023-1545

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

URVASHI BHAGAT,
Plaintiff-Appellant

v.

THE UNITED STATES PATENT AND TRADEMARK OFFICE, KATHERINE K. VIDAL, in her official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, UNITED STATES,
Defendants-Appellees.

On Appeal from The United States District Court For the Eastern District of Virginia, Alexandria Division, No. 1:20-cv-1515-CMH-IDD, Senior Judge Claude M. Hilton.

CORRECTED REPLY BRIEF OF THE APPELLANT[1]

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[1] This corrected reply brief reducing the word count is filed per Court order dated January 19, 2024, ECF No. 42.

STATEMENT OF REPRESENTATIVE CLAIMS

Appellant's Opening Brief separately presented and separately argued independent claims 82, 96-99, 112, and 115-116 (Br.ii-v; Br.48-64); and reserved additional arguments including on separate patentability of additional claims due to word limitation (Br.64).

Independent claims 82, 88, 96-99, 112, 115-116 and dependent claims 83-87, 89, 91-95, 100-104, 107-110, 113-114, 117-120 *contain significantly different limitations from each other as a whole* (Appx46-59) such that no claims are representative of the other for patentability determinations, as argued *infra* I.D.

TABLE OF CONTENTS

Page(s)
(As in original)

TABLE OF AUTHORITIES

Page(s)
(As in original)

CASES

UNITED STATES CONSTITUTION

STATUTES

RULES

STATEMENT OF RELATED CASES

Appellees cite *In re Bhagat*, 726 F. App'x 772 (Fed.Cir.2018) (Govt.Br.xiii[2]), however, besides injudiciousness of *In Re Bhagat* Non-precedential Opinion (Br.7-10), present claims remove alleged defects in the previous claims by *adopting legal remedies held in the Opinion*, e.g., defined lower and upper limit of dosages (*Id.* at 8) and express disclaimer of single source *in claims* rather than in prosecution (*Id.* at 3, 7). See comparison in Table 1 infra. Thus, *In Re Bhagat* supports patentability of present claims. Also see Br.54-56 and *infra* IX.

Table 1

In Re Bhagat, Independent Claim 65	Present Independent Claim 82
"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, (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	"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***

[2] Br.__, __ refers to Appellant's brief, and Govt.Br.__, __ to Appellees' brief. All emphasis is added unless otherwise stated.

not more than 40 grams."	***omega-6 fatty acid(s) and antioxidant(s) is not any single specific variety of a vegetable, a fruit, a nut, or a seed.***"

INTRODUCTION

Appellant objects to adverse signaling of her pro se status by Appellees (Govt.Br.1, *generally*) despite merits of her case[3]. Appellant has gained proficiency in law having prosecuted patents internationally through credible law firms and pro se since 2008 securing 36 patents[4].

Appellees' obstruction despite advancement potential from the inventions disclosed in US Patent Application No. 13,877,847 ("the '847 application") to save millions of lives and trillions of dollars in economic burden, while 18 corresponding patents are granted, is improper. Appellant's tone is prescribed by egregious violations usurping 15 years of her life (in three patent cases), and damages to public health by Appellees (Br.7-16, *generally*).

This Court ***must not*** rubber stamp errors below because ***exceptionally vital innovations for advancement in the art are at risk of permanent loss,*** which cannot be effectively implemented without the claimed scope and are not patentable to

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[3] *"The Signaling Effect of Pro se Status,"* Law & Social Inquiry, Fall 2017, https://law.indiana.edu/publications/faculty/2020/vdq-signaling-effect.pdf; *"Do Judge-Lawyer Relationships Influence Case Outcomes."* Harvard Business School. https://scholar.harvard.edu/files/tianwang/files/judges.pdf.

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

others after the disclosure. Br.5-10. ***"[A]dvancement in the art is the overriding constitutional standard... 'to be implemented by the [] courts.'"*** *In re Piasecki*, 745 F.2d 1468, 1473 (Fed.Cir.1984).

ARGUMENT

Arguments below demonstrate Appellees' and district court's repeated excision and distortion of facts and law, obstructing justice and oppressing Appellant, warranting reversal of orders below, recusal of judges, and sanctions on Appellees.

I. APPELLEES' STATEMENT OF ISSUES, CASE AND FACTS, AND STANDARD OF REVIEW MUST BE STRICKEN FOR CONTRAVENING FEDERAL CIRCUIT RULE 28(b) AND FOR FALSITIES AND LEGAL ERRORS

A. Contravention of Federal Circuit Rule 28(b)

Appellees' statement of issues, case and facts, and standard of review (Govt.Br.1-15, 18-19) must be stricken for failing to state areas of disagreements with those of Appellant (Br.2-12, 16), and making materially false statements.

B. Falsities/Distortions in Appellees' Statement of Issues

1. *Contra* Govt.Br.1, 3, subject action court was brought for conspiracy and bad-faith deprivation of constitutional rights to discoveries expressly invoking 28 USC §§ 1331, 1338(a), 1361, and 35 USC §145 in ***each of*** original Complaint (Appx65), *1st Am. Complaint* (Appx304), and Civil Cover Sheet (Appx322) which states,

VI. CAUSE OF ACTION	Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*: 28 U.S.C. §§ , 1331, 1338, 1361, 1391 and 35 U.S.C. § 145
	Brief description of cause: Abuse of process and Discretion in patent examination and improper rejections

2. *Contra* Govt.Br.1-2, this Court must first adjudicate Appellant's Issue Nos. 1-4 (Br.2-4) before adjudication of summary judgement because issues 1-4 affect adjudication of summary judgment.

3. Appellees ***falsify*** Appellant's motion to exclude USPTO's expert testimony was "based only on assertions of bias, not on admissibility" (Govt.Br.2; Br.34-41; *infra* VI).

4. Appellees ***falsify*** *2nd Am. Complaint* was based on information known to Appellant for months (Govt.Br.2) because motion for summary judgement (MSJ) raised new issues ***six weeks before*** *2nd Am. Complaint* was filed (Br.41-45; *infra* VII).

5. Appellees ***falsify*** MSJ was unopposed following close of discovery (Govt.Br.1) because close of discovery is under appeal and MSJ was opposed (Br.45-52; *infra* VIII).

C. Additional Falsities and Legal Errors in Appellees' Statement of Case

1. *Contra* Govt.Br.3 USPTO did not reject all pending claims as obvious, ***claim 112 was not rejected so*** (Appx6487).

2. *Contra* Govt.Br.3, 16, Appellant's appeal of orders placing higher litigation burden on her ***predates*** (Appx8326) MSJ (Appx8337).

3. Appellees **falsify** "The '847 Application Describes Nutritional Formulations Comprising Omega-6 Fatty Acids, Antioxidants, And Polyphenols" (Govt.Br.3), because the application teaches ***restricted proportional collective intake*** of omega-6 and antioxidants *including* polyphenols (Appx348-416 ¶¶ 3-4, 12-13, 75).

4. Appellees **falsify** the '847 application claims "greater than 5 mg of polyphenols" (Govt.Br.3), because independent claims recite, "dosage... from 25mg to 10g of antioxidants", "wherein the ***antioxidants comprise*** one or more polyphenols in the dosage of greater than 5mg" (claim 82, similarly claims 99, 112), and "the dosage of ***antioxidants includes*** at least 5mg of phytochemical(s)" (claims 115-116) (Appx46-59).

5. Appellees ***falsify*** the '847 application citing out of context statements "any orally acceptable form," "formulations may comprise nuts, such as almonds..." (Govt.Br.4). Specification, ***a legal instrument, requires*** **"the scope of the present invention is defined by the appended claims"** (Appx354 ¶22). *Markman v. Westview Instruments*, 517 U.S. 370, 388 (1996).

6. Appellees ***falsify*** the '847 application alleging "no method claim restricts an individual's total daily intake of these nutrients..." (Govt.Br.4), because many claims, including 99, 104(i), 109(iii), 110(iii) recite, "***daily dosage***", "***supplement, balance, or replace*** the individual's ***daily*** food consumption", "label [for] ***indication of the suitability,***" "food items that ***should not*** be included in the individual's daily diet..." (Appx52-54).

7. Appellees ***falsify*** the ***computer system*** alleging "computer programming... known in the art" (Govt.Br.5), because there is ***no §102 rejection*** against the claims (Br.53, 56; Govt.Br.12) and ***system*** in claim 112 provides *novel* remote access to consumers to develop *novel* tailored nutrition programs with *novel* claimed dosages (Appx55-56).

D. Falsities and Legal Errors in Appellees' Statement of Representative Claims

1. Contra Govt.Br.5, 39 Appellant's pleadings assert separate patentability of each claim (Appx311-312), and Opening Brief argues separate patentability of claims 82, 96-99, 112, 115-116, reserving arguments to additional claims (Br.ii-v, 48-64).

2. Each court is required to consider entire record for summary judgment. *Celotex Corp. v. Catrett*, 477 U.S. 317, 332, 337 (1986). The record asserts each claim is separately patentable, including pleadings (Appx311-312; Appx10965-10974), submissions to Patent Trial and Appeal Board (PTAB) (Appx4741; Appx4744-4751), expert reports (Appx7503-7536; Appx7630-7657), and opposition to MSJ (Appx9911-9913). Further, USPTO's ***professional opinion*** holds claims 115-116, substantially drafted by USPTO as "allowable", not representative of claim 82 (Appx3635-3636). ***PTAB decision is irrelevant to §101 grounds*** that were not before PTAB (Appx6487-6488). Courts may not use "representative claim" approach over inventor's objections. *Shelcore, Inc v. Durham Industries*, 745 F.2d 621, 624 (Fed.Cir.1984).

3. Both §§ 101, 103 grounds ***must be analyzed claim-by-claim*** because ordered combination of elements in claims, underlying facts, conventionality or lack thereof, and presence of inventive concept is relevant to both. *Mayo Collaborative Servs. v. Prometheus Labs.,* 132 S. Ct. 1289, 1294, 1297-1298 (2012); *Alice Corp. v. CLS Bank Intern.*, 134 S.Ct. 2347, 2355, 2357-2358 (2014); 35 USC §103.

4. Cavalier one-size-fits-all allegation of claim 82 as representative of progressively narrower ***8 independent claims, 18 product claims, 16 method claims, and 1 machine claim*** (Appx46-59), ***raises serious due process concerns.*** *Shelcore* 624. *Altoona Publix Theatres v. American Tri-Ergon Corp.,* 294 U.S. 477, 487 (1935) (reversing court of appeals "each claim must stand or fall, as itself sufficiently defining invention, independently of the others"); *Honeywell Intern. Inc. v. Hamilton Sundstrand,* 370 F.3d 1131, 1149 (Fed.Cir.2004).

E. Falsities in Appellees' Statement of USPTO Proceedings

Contra Govt.Br.6, PTAB determined "Morris teaches a dietary formulation comprising polyunsaturated fatty acids (e.g., omega-6 fatty acids) and vitamin E" (Appx5984); *not* "...formulations comprising omega-6 fatty acids, Vitamin E (an antioxidant), and polyphenols."

F. Falsities in Appellees' Statement on Diversity of Claims

Contra Govt.Br.8, all claims to damages, takings, misconduct, and mandamus are ***interrelated and interdependent*** originating from same conspiracy and bad-faith deprivation constitutional rights to discoveries. Appx297-318, Appx10914-10924, Appx10984-11026.

G. Falsities in Appellees' Statement of Discovery Facts

Contra Govt.Br.9-11, ***higher litigation burden*** placed on Appellant providing her 10% less discovery time ***was determining factor in delay*** of her

discovery completion (Br.26-33). Appellant requested additional discovery time to depose Dr. Harris, offered to make Dr. Erickson available for deposition, and demonstrated diligence in pursuing discovery (Appx7285, Appx7292, Appx8212-8230, *infra* V).

H. Falsities in Appellees' Statement of Motion to Exclude Their Expert

Contra Govt.Br.11, focus of Appellant's arguments was and is on ***inadmissibility*** of Appellees' expert testimony under Fed.R.Evid. 104, 402, 403, 405, 406, and 702, *Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993)* and *Sardis v. Overhead Door Corp., 10 F.4th 268, 282-283 (4th.Cir.2021)* (Appx7298-7304; Appx8241-8292; Appx8297-8299; Br.34-39; *infra* VI).

I. Falsities in Appellees' Statement of Summary Judgment Proceedings

Contra Govt.Br.12-15, MSJ ***was opposed*** asserting disputed facts "**Sufficient for Striking or Denying Defendants' Motion**" (Appx9913) and appeal of admissibility of Appellees' expert and close of discovery, which district court did not respond to until March 30, 2023, well after February 10th, 24th 2023 due dates for MSJ response brief and hearing (Appx9858-9864; Appx9910-9914; Appx19). It is flagrantly false to allege §§ 101, 103 rejections are undisputed when claims ***on the face disclaim*** "single specific variety of a vegetable, a fruit, a nut, or a seed...", which elements were ***not considered*** (Appx24-26; Appx46-59; Appx9911-9913), and when pleadings (Appx300-308), expert reports (Appx7130-7163; Appx7189-7203; Appx7429-7546; Appx7557-

7667), prior-art analyses (Appx7669-7714; Appx8260; Appx8264-8292) ***vociferously dispute facts.*** Moreover, district court ***admitted to disputed facts*** finding "Plaintiff asserts that Morris teaches away because its examples contain no or low amounts of omega-6 fatty acids and its antioxidant range," and "Plaintiff attempts to argue the prior art is not relevant..." (Appx31). Br.46-65.

J. Falsities in Appellees' Statement of Facts to 2nd Am.Complaint

Contra Govt.Br.15, Appellant notified Appellees in November 2022 that amendment was being drafted, which was delayed due to bad-faith discovery, paper filings, and new grounds and citations in MSJ ***six weeks before***; extra detail was added to matters ***already*** in *1st Am.Complaint* to obviate alleged "deficiencies" (Br.23, 41-45).

K. Distortions in Appellees' Standard of Review

Govt.Br.18-19 leaves out standards on due process violations including from unfairness of procedure, establishing new legal principle, manifest error of judgment, unfairly affecting outcome (Br.25), harmful errors (Br.34, 41), and claim construction (Br.54).

II. DISTRICT COURTS HAVE UNEQUIVOCAL JURISDICTION TO TRY DAMAGES FROM DUE PROCESS *AND* TAKING VIOLATION OF FIFTH AMENDMENT OF US CONSTITUTION UNDER §1331

A. District Court Never Ruled On §§ 1331, 1338

Contra Govt.Br.23, order below states, "Congress

has not waived its sovereign immunity for money damages in actions brought pursuant to ***35 U.S.C. § 145***. Any claims for money damages ***brought under this statute*** are dismissed for lack of subject matter jurisdiction." (Appx2-3). The court evaded §§ 1331, 1338 invoked in *1st Am.Complaint,* Civil Cover Sheet, and in opposition to dismiss (*supra* I.B.1, Br.17) in ***favoritism towards Appellees***.

B. Consent for Money Damages and Takings is *Unequivocally Expressed* in §1331 for "*All* Civil Actions Arising Under the Constitution [and] Laws" *and* Fifth Amendment Confirmed by Editorial Notes

Appellees admit §1331 expressly grants jurisdiction to district courts to try "***all*** civil actions [under Constitution and laws of United States]" (Govt.Br.24), and they do not dispute Appellant's argument "Editorial Notes to §1331 confirm 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" (Br.18). Thus, plain language of §1331 including Editorial Notes combined with Fifth Amendment for due process and Taking violations ***unequivocally express consent*** of United States to be sued under §1331 ***for monetary relief*** and grants jurisdiction for the same to district courts.

Supreme Court directive is "Our first step in interpreting a statute is to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case. Our inquiry must cease if the statutory language is unambiguous and 'the statutory scheme

is coherent and consistent.'" *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997).

Accordingly, the inquiry ***must cease*** because statutory language of §1331 is unambiguous that district court has subject matter jurisdiction for the 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 Plaintiff's life and business from ***violation of due process of law*** and ***Taking*** of Plaintiff's property without just compensation ***under Fifth Amendment of US Constitution***, that is likely to be redressed by favorable judicial decision.

Alleged "exclusivity" of claims against United States to Court of Federal Claims (Govt.Br.20-23) distorts the law. Supreme Court has held "jurisdiction is 'exclusive' only to the extent that Congress has not granted any other court authority to hear the claims that may be decided by the Claims Court." *Bowen v. Massachusetts*, 487 U.S. 879 n.48 (1988). Here §1331 ***specifically*** grants jurisdiction to district courts to hear ***all*** claims including due process and Takings claims "arising under the Constitution." "[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, limited only to the extent expressly barred under paired §702, and not barred under paired §704. *Bowen* 880 n.48. There is no statement in *Knick v. Township of Scott, 139 S. Ct. 2162 (2019)* holding exclusive jurisdiction of the Claims Court for Takings. Rather *Knick* reaffirmed

"Tucker Act is not a prerequisite to a Fifth Amendment takings claim." *Id.* 2174. Here, both compensatory monetary reliefs are mandated under the Fifth Amendment (1) for injury suffered from due process of law violations (unfair proceedings), and (2) Taking of property from regulatory delay, expressly provided in §1331 and not barred in paired statues §§ 1338, 145. (Br.17-21).

C. District Court Has Jurisdiction to Try Due Process Violations Irrespective of Patentability, Further Federal Rule 18 Permits Joining of Takings Claim Contingent Upon Disposition of Patentability

Regarding "time" of claim (Govt.Br.22), bad faith and conspiracy to deprive constitutionally protected rights to discoveries for about 8 years are due process of law violations (unfair proceedings) under Fifth Amendment causing injury to Appellant's life and business (property rights) (Br.11-12, 17, Appx298-317; Appx525-547) that can be redressed with compensatory damages under §1331, irrespective of patentability. *Davis v. Passman*, 442 U.S. 228, 231, 236, 243-244, 403 (1979). Further, Fed.R.Civ.P.18(b) permits joining of Takings claim even if contingent upon patentability determinations.

III. COMPLAINT SUFFICIENTLY STATES FACTS TO DEPRIVATION OF CONSTITUTIONAL RIGHTS TO DISCOVERIES, MISCONDUCT, FALSE STATEMENTS, AND ENTITLEMENT TO MANDAMUS

District court's regurgitation of Appellees' motion to dismiss (Appx2), and Appellees' advancement of same as "court explained" (Govt.Br.26), alleging *1st Am. Complaint* contains no facts to violation of constitutional rights, misconduct, false statements, and entitlement to mandamus relief are ***flagrantly false*** and confirm district court's ***favoritism towards Appellees.***

To allege Complaint that repeatedly cites "bad faith and disingenuousness in examination and appeal review, despite being aware of Plaintiffs constitutional rights" citing "Constitutional Basis, Art. 1, Sec. 8" for rights to discoveries (https://www.uspto.gov/web/offices/pac/mpep/mpep-0020-introduction.html) (Appx298-299 ¶¶2-3, n.3; Appx316-317 ¶¶76-83), somehow "fails to identify 'even what constitutional right was violated'" (Appx6; Govt.Br.27) and despite identical assertions in opposition to dismissal (Appx550) ***warrants recusal.***

Reproductions from Complaint are precluded by word limit (Br.34 n.27; ECF.No.42), but Complaint, Appx298-314 (¶¶ 2-3, n.2, 11, 36-41, 45, 48, 55-63, n.6) abundantly states facts to false statements, misconduct, and violation of constitutional rights to discoveries. *Contra* Govt.Br.26-27, cited statements are detailed, and Br.22 asserts "right to patents is grounded in the US Constitution, which was violated by USPTO bad faith." Also see *2nd Am. Complaint* Appx10984-11015.

Rule 12(b)(6) orders are reviewed ***de novo.*** *Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th.Cir.1999). "[w]e must be especially solicitous of the wrongs alleged [for due process violations]" and "must not dismiss the complaint unless it appears to

a certainty that the plaintiff would not be entitled to relief under any legal theory." *Harrison v. United States Postal Serv.*, 840 F.2d 1149, 1152 (4th.Cir.1988). Fed.R.Civ.P.8 does not require citation of statute, which can be inferred from pleadings. False statements and misconduct to deprive constitutional rights to discoveries constitutes unfair proceedings and violation of due process of law, having cause of action in invoked §1331; additionally, 18 U.S.C §1001 can be inferred.

IV. SEVENTH AMENDMENT GUARANTEES RIGHT TO JURY TRIAL TO PREVENT ABUSE OF POWER AT ISSUE

Our Declaration of Independence from King of Great Britain states,

> "He has refused his Assent to Laws, the most wholesome and necessary for the public good... ...depriving us in many cases, of the benefits of Trial by Jury." [5]

Bill of Rights comprising the Seventh Amendment was instituted to prevent abuse of powers and extend public confidence in Government[6]. Seventh Amendment entitlement to jury trial is rooted in preventing very abuse of power—evident here. Govt.Br.28-29 flies in the face of Bill of Rights. No rule, statute, or legal theory posited by Appellees supersedes Constitution of the United States.

Distinctive circumstances of subject litigation ***demand*** trial by jury because United States has in conspiracy obstructed important innovations in

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[5] https://www.archives.gov/founding-docs/declaration-transcript
[6] https://www.archives.gov/founding-docs/bill-of-rights

nutrition arts, subjecting public to drugs, devices, and pandemics, abusing the public (Appx298-318; Appx10914-11027; Br.4-67). United States and its agencies (USPTO and judiciary) have demonstrated inability to be objective in the matter.

Contra Govt.Br.29, even if *Law v. United States*, 266 U.S. 494, 496 (1925); *Hepner v. United States*, 213 U.S. 103, 115 (1909); and *United States v. Regan*, 232 U.S. 37, 47 (1914) were brought by United States, the dispositive point is they uphold trial by jury against United States.

Contra Govt.Br.29, Jury trial is demanded under §1331, not §145.

Fed.R.Civ.P.39(a) provides discretion to institute jury trial. Fed.R.Civ.P.39(c) bars jury trial against United States *only* when "federal statute provides for a nonjury trial," inapplicable here.

Jury trial should be granted, even if advisory jury is appointed, proposed previously (Appx551-553).

V. DISTRICT COURT DID NOT PROVIDE APPELLANT EQUAL ACCESS TO JUSTICE AND EQUAL PROTECTION OF LAWS VIOLATING DUE PROCESS UNFAIRLY AFFECTING OUTCOME

A. District Court Unjustly Reduced Appellant's Discovery Time by About 10% From Paper Filings Unfairly Affecting Outcome

Contra Govt.Br.48-49 Appellant asserts ***right to fair proceedings*** and that paper filings reduced Appellant's discovery time over Appellees, and her chance to respond. ***Due process violation is in unfairness of procedure and harmful outcome.***

Br.25-27. *Snyder v. Com. Of Mass.*, 291 U.S. 97, 116, 137 (1934). *Newell. Co. v. Kinney Mfg.*, 864 F.2d 757, 765 (Fed.Cir.1988). *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 546-548 (1985).

Appellees distort facts and law, exemplified below:

Table 2	
Distortions in Govt.Br.49-50	**Facts/Law**
"Indeterminate Amount of time"	"about 12 days or 96 hours" Br.26
"mailed the paper...*after* its due date" "still considered by the court"	Due date 10/12/22; extension requested 10/11/22 (Appx8201-8202); brief mailed 10/13/22 (Appx7228); docketed 10/18/22 (Appx39 #57). Not considered. Appellant's asserted objections including trade secrets (Appx7116-7123) were disregarded (Appx7085) Appellant expressed frustration over not being heard (Appx8195-8197).
"Table 2 shows no filings by Bhagat during...period for discovery"	When 12 days for paper filing are ***backed out*** from dispatch date of Appellant's motions for discovery enlargement and expert disqualification (Table 2 Br.13), the filing date is 11-29-22, ***10 days before*** discovery close. 12 days must be similarly backed out from other discovery filings: Appx39-41 nos. 57, 62-66, 70-74, 76.
"motion to amend was	Close of discovery is under

filed...three months after the close of discovery	appeal (Br.3). Motion to amend aggregates ***new*** issues from discovery and MSJ filed ***six weeks before***. Br.43-45.
"motion to amend was considered by the court"	***Not considered***. Case was dismissed while motion to amend was pending "without justifying reasons" (Appx34) violating *Foman v. Davis*, 371 U.S. 178, 182 (1962).

B. District Court Does Not Have Discretion to Violate Federal Rules 6, 16, and Supreme Court Precedent Lujan, in Requiring Written Motion for Extension Requests Before Expiry of Time

Contra Govt.Br.47 Appellant never cited EDVa Rule 7(F), inapplicable to discovery; Appellant cited EDVa Rule 26(B) pertaining to discovery, similar to Fed.R.Civ.P.6(b)(1)(A) providing extension of time ***requests can be made without paper motion*** "if a request is made before the original time [] expires." Local rules are required to be consistent with Federal Rules. Br.29-30.

Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 896 n.5 (1990) confirms, "Rule 6(b)(1) allows a court...to grant a "request" for an extension of time..."with or without motion or notice," provided the request is made before the time for filing expires." Advisory Committee Notes on Fed.R.Civ.P.16(b)(4) also confirm "a formal motion is not necessary [to] modify the schedule."

Contra Govt.Br.43, 47, discretion is ***limited*** to grant, but court ***is required to accept the request*** for

extension of time "***without motion or notice [ex parte]***" before time for filing expires, as requested. Br.28-29.

C. Without Neglect Appellant Requested Extension Before Time Expiry

Per Rules 6, 16, and *Lujan,* Appellant made five requests for extension of discovery time, November 20-22 and December 1-5th 2022, ***before close of discovery*** on December 9, 2022, for good cause including ***two medical emergencies*** asserting ***paper motions will not reach the court on time*** especially because of Holidays. Each request was made under *increasing* time constraints and *increasing* experts' absence from illness (Appx7292-7294). Br.28-30. Additionally, written motion should be considered filed on 11-29-22, 10 days before discovery close (Table 2 *supra*).

D. Appellant Established Good Cause for Discovery Enlargement

Appellant demonstrated "[schedule] cannot reasonably be met despite [her] diligence" (Fed.R.Civ.P.16(b)(4) Notes). Appellees and district court distorted facts to marginalize good cause, exemplified below:

Table 3

Distortions in Govt.Br.44-46	**Facts**
"no filings during entire discovery period"	Debunked in Table 2 *supra.*
Inaction until November	***No inaction:*** Appellant was consumed with discovery from July 2022-January 2023. Appx38-41.

Response to Appellees' discovery versus pursuit of her own discovery	Appellant worked round-the-clock to meet deadlines (Br.26-33; Appx8220-8229). Discovery deadlines ***beyond Appellant's control were met first***, delaying her own discovery. Appx8222-8223.
Appellant had "three months...to take depositions"	She could not take depositions until ***exposing bad-faith*** Appellees' expert report on December 9th. Br.32, 35-37.
Unintentional timing	Court ***maliciously*** denied discovery enlargement ***1 day before*** final pre-trial conference on January 12, 2023, evidenced by orders of December 16th, 30th (Appx9-12) acknowledging motion for discovery enlargement, finding time to ***bar*** Appellant's emails and calls, ***but withholding ruling***, while extension to Appellees was granted within a day. Br.31-32.

Good cause is lower standard than "manifest injustice" (offense to judicial propriety) (Fed.R.Civ.P.16(b)(4) Notes). Here denial of discovery enlargement is manifest injustice. This Court must reverse and remand with order to accept timely oral and email motions for time extension going forward.

VI. APPELLEES FALSIFY FACTS AND COMMIT LEGAL ERROR VIOLATING SUPREME COURT'S *DAUBERT* MANDATE TO ALLEGE MOTION TO EXCLUDE THEIR EXPERT WAS

ENTIRELY BASED ON BIAS AND DENIAL WAS HARMLESS

District court disregarded 33-page briefing and 500-page evidence asserting "Harris' opinions and testimony ***lack any indicia of admissibility*** under *Daubert* and the Federal Rules of Evidence 104, [402], 403, 405, 406, and 702" (Appx8242; Appx7298-7304; Appx7309-7762; Appx8241-8292; Appx8297-8299) and reflexively denied the motion under ***pretexts*** of bias not admissibility. Br.34-35.

Appellees falsify facts and law, as exemplified below:

Table 4

Falsities in Govt.Br.50-52	Facts/Law from Briefs in Support of Motion to Exclude
"her reasons for exclusion were based ***entirely*** on allegations of bias"	"***and*** his opinions and testimony are ***neither relevant nor reliable*** pursuant to the standards set forth in *Daubert*...likewise ***inadmissible*** because any probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, waste of time, undue delay, and needless presentation of cumulative evidence. See Fed.R.Evid.403." Appx7298. "HARRIS' REPORT, OPINIONS, AND TESTIMONY LACK PROBATIVE VALUE AND ARE THUS INADMISSIBLE UNDER FEDERAL RULE OF EVIDENCE 403 ...Court should exclude evidence if its introduction will result in unfair prejudice, confusion of the

	issues, or result in misleading testimony. Fed.R.Evid.403. ...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 Plaintiffs disclosure, state of the prior art, and the law." Appx7304.
"Bhagat...failed to support any challenge to the ***methodology*** used in his report, and did not assert that his report was in anyway ***unsupported.***"	"Harris Report massively reconstructed prior art while mutilating the claims and disclosure of the Plaintiff's US Patent Application no. 13/877,847" Appx7299 "Harris has (1) massively denigrated the '847 application, (2) he has mutilated the pending claims to support rejections, (3) he has massively restructured the prior art to allege obviousness, (4) he has reviewed the prior art in bits and pieces, and only the parts that support his position... and (5) he has imposed his own interpretation of the law as to assessment of

	priority, claim interpretation, obviousness, unexpected results, and secondary considerations." Appx7300 "Not based on sufficient facts...not based on reliable principles and methods...not reliably applied the principles and methods to the facts of the case" "(iv)...contradicted his own recently published statements," "(vi)-(vii)... has not reliably applied the principles and methods to the facts of the case in considering the claims as whole against the cited art," and "in assessing secondary considerations" (Appx8246-8252; Appx7695-7714; Appx8264-8292).
District court did not rely on Harris testimony for §101 analysis. "Bhagat was not harmed..."	Harris testimony created unfair prejudice, and confused issues. Fed.R.Evid.403. District court ***explicitly*** (Appx30-31) ***and implicitly*** (Appx25-29) relied on Harris testimony in its opinion and decision granting summary judgment for rejection of claims of the '847 Application, by ***same*** mutilation of the disclosure and claims (Appx25-27; Appx7352-7358), ***same*** reconstruction of prior art to allege §103 obviousness (Appx30-3; Appx7359-7363), and ***same*** rejection under ***§101*** citing ***same*** art "almonds," as suggested by Harris testimony, not cited by USPTO (Appx25; Appx7342-7349).

	Without Harris testimony, Appellees ***failed to meet their evidentiary burden*** for "widely divergent conditions" (Appx28) and "well-known/conventional [in the art]" even for ***§101*** determinations (Appx27, Appx29). Br.39-41; *infra* IX.B.

Appellant ***vociferously challenged*** Harris opinion as ***irrelevant, unreliable, and inadmissible*** before district court, yet the court failed to make explicit findings (Appx17) required by *Daubert* and *Sardis 282-283*, and the admission was harmful legal error compromising Appellant's substantial rights. This Court must reverse.

VII. APPELLEES FALSIFY FACTS AND COMMIT LEGAL ERROR TO ALLEGE DELAY, PREJUDICE, AND FUTILITY TO OPPOSE ENTRY OF 2nd AMENDED COMPLAINT VIOLATING SUPREME COURT'S *FOMAN* MANDATE

Contra Govt.Br.52 district court does ***not*** have discretion to outright refuse "to grant the leave [to amend] without any justifying reason." *Foman* 182. District court did not justify why summary judgment alleging "no issues of material fact" denying patentability under §§ 101, 103 was granted (Appx24), while *2nd Am. Complaint* ***disputing new issues raised six weeks earlier was pending*** (Appx34) with "underlying facts [and] circumstances relied upon by plaintiff [for] proper subject of relief" (*Foman* 182) vociferating over 60 pages claims are

clear of §§ 101, 103 (Appx10924-10984). Br.43-45.

Appellees distort facts and law to oppose entry of *2nd Am. Complaint* exemplified below:

Table 5	
Distortions in Govt.Br.52-54	**Facts/Law**
"Information Appellant knew for months,"	Appellant ***did not know*** of new §§ 101, 103 rejections with specificity until MSJ was filed ***six weeks before***. Br.43-45.
"Progress", renewed motions, "need to clarify," "prejudice."	Alleged progress is ***disputed***: discovery is not completed, depositions are not taken, Appellees' expert is objected, claim construction hearing is not held, facts are disputed, and summary judgment fails as matter of law. Br.31-32, 46-66, *infra* VIII-IX. Dismissals are improper including for failing to recognize §§ 1331, 1338, and so would be renewed motions. *Supra* II-IV; Br.16-24. Supplemental facts and jurisdictional statutes under each count (Appx10984-11026) were added not for "need", but to obviate ***pretexts*** of deficiency. Br.45. Amendments derive from matters (1) already in *1st Am. Complaint,* (2) from discovery and MSJ, and (3) nature of litigation stays the same. Br.42-43. Legal

	standards of prejudice are not met. *Edwards* 240-243.
"Futility"	*No futility* because no statute of limitations, preemption, or waiver is at issue. *Equal Rights Center v. Niles Bolton Assocs.*, 602 F.3d 597, 604 (4th.Cir.2010). Amendment is not insufficient or frivolous on the face. *Johnson v. Oroweat Foods Co.*, 785 F.2d 503, 510 (4th.Cir.1986).

Not granting proposed amendment is manifest injustice. Considering egregious due process violations by district court discussed above and at Br.41-45, 66-67, this Court must reverse the denial of entry of *2nd Am. Complaint* and preempt improper "renewed motions" by reversing improper dismissals considering Br.16-24, supra II-IV, and *2nd Am. Complaint.*

VIII. APPELLEES FALSIFY FACTS AND DISTORT THE LAW TO JUSTIFY PREMATURE SUMMARY JUDGMENT

A. MSJ Grant While Discovery Close is Appealed Violates *Celotex, Harrods*, and Rules 6(b), 16(b), 56(b)-(d)

Contra Govt.Br.30-31, alleged "lengthy discovery...not diligent" are distortions and oppressions refuted *supra* V and Br.25-34. Permitting preemption of interlocutory appeal on unfair discovery procedures and orders with summary judgment would derail "the Federal Rules as a whole," including Rules 6(b), 16(b), 56(b)-(d). *Celotex* 327; Br.46-47.

Contra Govt.Br.31, *Harrods Ltd. v. Sixty Internet Domain Names*, 302 F.3d 214, 245-247 (4th.Cir.2002), held district court erred in granting summary judgment where "nonmoving party's objections before the district court served as the functional equivalent of an affidavit" under Rule 56(d) and "the nonmoving party [as Appellant] was not lax in pursuing discovery." *Supra* V; Br.25-34. *Contra* Govt.Br.32, Appellant asserted, "discovery of additional facts is necessary, including to identify witnesses for trial...expressly provided [in Rule] 56(d)." Appx9913.

B. MSJ Grant Relying on Appellees' Objected Expert Testimony Violates Rule 56(c)(2)

Contra Govt.Br.38 n.14, district court *did* rely on Harris testimony for §101 (*supra* VI; Br.40). Further, Appellees *admit* "[district court] relied on the [Harris] testimony in addition to other evidence" for obviousness (Govt.Br.42), violating Fed.R.Civ.P.56(c)(2). Br.47-48.

C. Appellant' Motion to Strike/Deny MSJ Is Functional Equivalent of *Opposition* Affirming Issues of Material Fact *Admitted* by District Court

Contra Govt.Br.33 Appellant's memoranda are functional equivalent of opposition (Br.51) which affirm, "motion for summary judgment should be stricken or ***denied***," (Appx9863; Appx9913) citing ***specifically*** disputed facts: claims expressly disclaim single source like almonds and include numerous other limitations that do not occur in nature, like formulations/composition of matter, packaging labeling, individualized, and tailored dosages. (Appx9911-9912). Therefore, "proof concerning an

essential element" of Appellant's case, per *Celotex* 322-323 *is provided in the claims and in cited* pleadings with proof beyond allegations (published evidence), expert testimonies, published papers, and prior art analyses on record. Br.49-51, 58-61. Therefore, *Contra* Govt.Br.32-33, Appellant did oppose MSJ and "properly address another party's assertion of fact" per Fed.R.Civ.P.56(e).

Moreover, district court ***admitted*** to disputed facts. *Supra* I.I.

To allege "no genuine dispute as to any material fact" (Govt.Br.29, 32-33) on record bursting with disputed material facts of Appellant's case (Br.49-51, 58-61) is to *knowingly make false statements* warranting sanctions.

D. Appellees Admit Claim Construction is Disputed and Do Not Dispute Lack of Hearing

Govt.Br.35-38 admits claim construction and related facts are disputed (Appx9911-9912), and do not dispute required claim construction hearing was not held. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1370 (Fed.Cir.2018). Br.48-49.

IX. SUMMARY JUDGMENT ON PATENTABILITY FAILS AS MATTER OF LAW

A. District Court *Revictimized* Appellant by Non-Consideration of Disclaimer of Single Source Under §101 and Poorly Understood Factors Under §§ 101, 103; *and* Appellees Violate *Celotex* and *Custer* in Alleging Forfeiture

It is an embarrassment to judiciary when Complaint is brought *for bad-faith* deprivation of rights to discoveries asserting,

> "USPTO tried to force 35 U.S.C. §101 rejection over multiple Office actions, even though the Plaintiff expressly disclaimed products of nature in the claims [] The rejections were reversed after multiple petitions but after wasting two years in prosecution and a whole lot of expense." (Appx298 ¶2); and
>
> "[USPTO disregarded] 99% of arguments and 100% of the evidence (scientific papers evidencing poorly understood factors)" (Appx299 ¶3; Appx301-302; Appx305-307);

Defendants *repeat bad-faith resurrecting* §101 rejection, which is opposed re-asserting the disclaimer and poorly understood factors (Appx9911-9912) citing expert testimonies (Appx7452 ¶59; Appx7580 ¶59) and publications on record (Br.58-61), yet violating *Celotex* 322-26 and *Custer* 415-16 district court *revictimizes* Plaintiff disregarding Complaint, briefs, and record (Appx25, Appx30-31) and in *further bad-faith* Appellees allege forfeiture (Govt.Br.35-36, 40).

There is ***no*** forfeiture of disclaimer and poorly understood factors arguments:

(i). those have been argued in *1st Am. Complaint* (Appx298-302; Appx305-307), *2nd Am. Complaint* (Appx10924-10982), in opposition to MSJ (Appx9911-9912) citing expert testimonies and numerous publications on record (Appx7452 ¶59; Appx7580 ¶59; Br.58-61), and on administrative record

umpteen times (Appx3622; Appx3807-3834; Appx10987-10994), which must be considered for summary judgment per *Celotex* 322-26 and *Custer* 415-16;

(ii). *each court* must review *entire record* mandated by Rule 56, *Celotex* 322-26;

(iii). the disclaimer of single source is *incontrovertible,* and contradiction of claim terms is prohibited (Br.54-55); and

(iv). this Court reviews both §§ 101, 103 as legal conclusion subject to full independent review without deference. *AT&T Corp. v. Excel Communications,* 172 F.3d 1352, 1355 (Fed.Cir.1999); *Continental Can Co. USA, v. Monsanto*, 948 F.2d 1264, 1270 (Fed.Cir.1991).

B. Forced Patent-Ineligibility Allegations Violate Congressional and Supreme Court Mandates 35 USC §§ 100(b), 101, Mayo, Myriad, Alice, and Markman

Contra Govt.Br.34 n.13, §101 rejections were repeated improperly by USPTO for years during prosecution and were **withdrawn after multiple responses and review petitions** (Appx298; Appx3622; Appx10986-10993). Despite extensive administrative record refuting and withdrawing §101 rejections and Appellant's cogent arguments (Br.52-57) Appellees have distorted facts and law to *reallege* ineligibility.

Instant Claims Are Patent-Eligible ***at Alice Step One:***

Appellees do not dispute applicants can incontrovertibly disclaim matter, *Abbott Laboratories v. Sandoz, Inc.,* 566 F.3d 1282, 1288 (Fed.Cir.2009)(en banc), and the '847 Application is a legal instrument requiring "the scope of the present invention is defined by the appended claims" (Appx354 ¶22), *Markman* 517 U.S. 370, 388, and contradiction of claim terms is prohibited, *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed.Cir.1995) (en banc).

Further, *Contra* Govt.Br.36 and district court's allegations (Appx26), instant claims *may comprise* nuts like almonds (claims 95, 103), but "comprising" does not exclude additional elements. *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376 (Fed.Cir.2004). Therefore, even if dependent claims recite comprising nuts, the disclaimer to single source confirms additional elements are present in claims even if nuts like almonds are present. Claims must be interpreted ***as a whole***. *Mayo* 1298; *Alice* 2355 n.3; Br.55-56; *supra* I.C.5.

Furthermore, *Contra* Govt.Br.36-37, *In re Thorpe*, 777 F.2d 695, 697 (Fed.Cir.1985) is inapplicable to §101, controlled by §§ 100(b), 101, *Mayo, Myriad,* and *Alice*. *Myriad* held "dictated by nature is not the test" finding cDNA, and mutatis-mutandis present mixtures to be patent-eligible. *Ass'n for Molecular Pathology v. Myriad Genetics*, 569 U.S. 576, 579, 595 (2013). Appellees cannot cite a single precedential decision finding claimed "mixtures" to be patent ineligible. Moreover, instant claims incorporate guidance from *In re Bhagat,* expressly disclaiming single source *in claims*. *Supra* Statement of Related Cases.

> "[a]t step one, "it is not enough to merely identify a patent-ineligible concept underlying the claim; we must determine whether that patent-ineligible concept is what the claim is 'directed to.'" *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed.Cir.2016). If the claims are not directed to a patent ineligible concept at step one, we need not address step two of the inquiry." *Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1134 (Fed.Cir.2018)

Instant claims are simply *not* directed to patent-ineligible concept. Br.52-55.

Arguendo, Instant Claims Are Also Patent-Eligible ***at Alice Step Two****:*

Contra Govt.Br35, Appellant does dispute almonds can provide dosage of any nutrient (Appx307 ¶31; Appx10924-10927).

Contra Govt.Br.37-38, Appellant detailed at Br.55-56 the numerous elements in ***ordered combination*** that were left out, besides the disclaimer, by district court.

District court failed to analyze *ordered combination* "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" (claim 82). District court (Appx25-29) and Govt.Br.34-38 also fail to explain what amount of almonds is product of nature, and how does that amount provide the claimed collective dosages, and provide *no analysis* of "suitability for consumption", "collectively provide a [daily] dosage" of "1 to 40g" and "25mg to 10g" and (claims 82, 99, 115-116) and "remote user inputs" to

determine diet cohorts (claim 112) (*supra* I.C.7).

Claimed "collective/daily" dosages of "1 to 40g" and "25mg to 10g" "labeled indicating suitability for consumption" for "diet cohort" are new processes under §§ 100(b), 101 and are patent eligible. *Contra* Govt.Br.37, claims ***as a whole in "ordered combination"*** are not directed to "well understood, routine, or conventional activity," and are patent-eligible products, processes, and machines designed/programmed to solve a ***complex problem***. *Alice* 2355, 2358-2359; Br.55-56.

Further, without Harris testimony (*supra* IV; Govt.Br.38 n.14), district court has no evidentiary basis for "well-known," "routine," and "conventional" in the art pertaining to all claims (Appx27-29), and "widely divergent conditions" pertaining to claims 96-98 and 116 (Appx28). District court *impermissibly* substituted their opinion for that of skilled artisan on "conventionality" disregarding overwhelming evidence of poorly understood factors (Br.58-64). "[t]he concern of hindsight bias has as much relevance to a §101 challenge as it does a §103 challenge." *Ameritox, Ltd. v. Millennium Health,* 88 F.Supp.3d 885, 914 (W.D.Wis.2015).

Furthermore, this Court has recognized evidence of novelty (Br.53, Br.56) may well support finding of inventiveness or non-conventionality at Mayo/Alice Step Two. *Rapid* 1047.

District court's erroneous patent-ineligibility opinion must be reversed.

C. Forced Obviousness Rejections Violate Congressional and Supreme Court Mandates 35 USC §103 and *Graham*

Contra Govt.Br.41-42, *inadmissible* Harris testimony relied upon for §103 must be first *excluded* before §103 determinations, as shown *supra* I.H., VI, Br.34-41, Br.57-58. *Weisgram v. Marley*, 528 U.S. 440, 453–56 (2000). Further, alleged "failure below to identify any disputed material facts" is *fausse*, as shown *supra* I.I., VIII.C. Therefore, district court improperly weighed evidence. Br.47-48.

The poorly understood factors, long-felt but unsolved need, and failure of others (Br.58-64) alone warrant reversal of §103 rejections. *Graham* 17, *Piasecki* 1475, *Loctite Corp. v. Ultraseal,* 781 F.2d 861, 873 (Fed.Cir.1985), *Continental* 1270.

Appellees ***falsify*** facts and commit legal errors to force obviousness, exemplified below:

Table 6

Falsities in Govt.Br.39-41	**Facts/Law**
"prior art combinations" teach "dosages of omega-6 fatty acids, antioxidants, and polyphenols"	*None* of them alone or in combinations teach dosage of *total* antioxidants comprising polyphenols. Appx8266-8267; Appx8270-8271; Appx8275-8276; Appx8280-8281; Appx8285; Appx8287-8288; Appx8291.
Prior art is not "irrelevant because it does not address the problem"	Results-effective variable is not taught in prior art. Appx7148; Appx7151; Appx7199; Appx7201; Appx7533-7534; Appx7655. Appx10958-10975. To force obviousness, Appellees have selectively culled elements from *500+* vague alternatives in prior art, too frequently falling outside claimed dosage ranges,

	and reconstructed prior art in hindsight, violating many precedents including, *ATD Corp. v. Lydall,* 159 F.3d 534, 546 (Fed.Cir.1998) and *Ruiz v. A.B. Chance*, 234 F.3d 654, 665 (Fed.Cir.2000). Prior art did not have reason to combine elements as claimed because problem is not understood. *KSR Int'l Co. v. Teleflax,* 127 S.Ct. 1727, 1731 (2007).
Appellant does not dispute that "prior art discloses the claimed nutrients in dosages overlapping the claimed dosages"	It is ***disputed*** including: Morris discloses *universe* of antioxidants/ polyphenols *not* dosage "flavonol anti-oxidant (e.g., baicalein)." Appx306-307 (Appx9412 ¶128); Appx8267; Br.62. Each of Howard, Debbouz, and Rusing fail to teach dosage of *total* polyphenols. Appx8276; Appx8285; Appx8291 Appellant's expert testimonies affirm prior art does not disclose overlapping dosages. Appx7480-7482; Appx7524-7526; Appx7608-7610; Appx7649-7650; Appx10958-10975.
"no claim restricts an individual's total daily intake of the claimed nutrients"	Dosage means restriction (Br.56), "daily dosage" is recited in claim 99 and dependent claims (104, 109-110, *supra* I.C.6), affirmed by experts (Appx7138; Appx7454; Appx7527; Appx7581-7582; Appx7651)

Appellant did not show the prior art taught away	Appellant abundantly demonstrated teaching away including at Br.59, Br.62-63, affirmed by experts Appx7481-7490; Appx7503-7506; Appx7518-7522; Appx7530; Appx7609-7618; Appx7631-7634; Appx7653; Appx7644-7647; Appx10960-10975.
"Morris's examples with dosages of omega-6 fatty acids or antioxidants outside the claimed ranges do not teach away"	Morris examples *do not* disclose dosage of antioxidants including polyphenols. Br.62 and *supra*. Morris' examples contain *no* or *0.070g* omega-6, there would be no expectation of success from Morris to arrive at claimed inventions teaching *571x* omega-6 over Morris (Br.59, Br.62-63) testified by experts. Appx7144-7151; Appx7200; Appx7481-7482; Appx7609-7610. *Amgen v. Chugai Pharm.*, 927 F.2d 1200, 1208 (Fed.Cir.1991) (obviousness requires reasonable expectation of success).
Appellant did not show unexpected results... "results showing a benefit only at 11 g or higher of omega-6 fatty acids are not sufficient to establish unexpected results across the full range of 1 to 40 g"	Appellant abundantly demonstrated unexpected results, Br.62-63, affirmed by experts that they can achieve the results through whole diets and/or supplementation. Appx7514-7518; Appx7641-7644; Appx10975-10977. Evidence of nonobviousness of broad range can be proven by a narrower range when skilled person could ascertain a trend allowing him to extend the

	probative value thereof. *In re Clemens,* 622 F.2d 1029, 1036 (CCPA 1980).

District court's erroneous obviousness opinion must be reversed. "[A]dvancement in the art is the overriding constitutional standard...'to be implemented by the [] courts.'" *Piasecki* 1473.

X. RECUSAL OF JUDGES BELOW AND SANCTIONS ON APPELLEES ARE WARRANTED

Critical question presented by 28 USC §455(a) "is not whether the judge is impartial in fact. It is simply whether another, not knowing whether or not the judge is actually impartial, might reasonably question his impartiality on the basis of *all the circumstances*." *Hathcock v. Navistar Int'l Transp. Corp.*, 53 F.3d 36, 41(4th.Cir.1995); *Aiken County v. BSP Division of Envirotech Corp.*, 866 F.2d 661, 679 (4th.Cir.1989). "The hypothetical reasonable observer is not the judge himself or a judicial colleague [as Appellees] but a person outside the judicial system." *United States v. DeTemple*, 162 F.3d 279, 283 (4th.Cir.1998).

Contra Govt.Br.55, "all the circumstances" here, *substantially disregarding Appellants' every single pleading and argument and distorting the law against her, silencing her, and pressing her to withdraw the action*, (Br.66-67, *generally* and this brief, *generally)* evidence "[excessive] degree of favoritism or antagonism required" for recusal per *Liteky v. United States*, 510 U.S. 540, 555 (1994).

Contra Govt.Br.55, transcript demonstrates Appellees are allowed to speak uninterrupted (Appx9919-9922), Appellant cordially pleads to get a

word in repeatedly but is silenced every time (Appx9922-9948), and her frustration (Appx9943-9945).

Additionally, the transcript has been altered from original recording in favor of the court and Appellees. Complaint to National Court Reporters Association filed August 7, 2023, is pending.

Therefore, "the probability that a judge will decide a case on a basis other than the merits [is] more than 'trivial.'" *In the Matter of Mason*, 916 F.2d 384, 386 (7th.Cir.1990).

The recusal below could not be sought in time. For judicial economy avoiding further motions and appeals, this Court should order recusal of Judges Hilton and Davis.

Further, this Court must assess sanctions against Appellees per *Alyeska Pipeline Service Co. v. Wilderness Society*, 421 U.S. 240, 258-260 (1975) (holding federal courts have discretion to assess sanctions when a party has acted in bad faith, vexatiously, wantonly, or for oppressive reasons). Appellees acted in bad faith oppressing Appellant for over 10 years with mindless rejections (Appx10984-11015). They oppress her further in the subject action ***resurrecting §101 rejections withdrawn after years of prosecution and review petitions***, and falsify facts and law discussed throughout this and Opening Brief.

CONCLUSION AND RELEIF SOUGHT

This Court must order relief requested above and in Opening Brief.

Urvashi Bhagat, Pro se Appellant

THE UNITED STATES CONSTITUTION, STATUTES and TREATIES

U.S. Constitution, Article I, Section 8, Clause 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."

U.S. Constitution, Amendment V:

> "No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation."

U.S. Constitution, Amendment VII:

> "In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law."

28 U.S. Code § 1331 - Federal question:

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

Historical and Revision Notes (excerpts):

...Jurisdiction of federal questions arising under other sections of this chapter is not dependent upon the amount in controversy...

Amendments (excerpts):

1980-Pub. L. 96–486 struck out "; amount in controversy; costs" in section catchline, struck out minimum amount in controversy requirement of $10,000 for original jurisdiction in federal question cases which necessitated striking the exception to such required minimum amount that authorized original jurisdiction in actions brought against the United States, any agency thereof, or any officer or employee thereof in an official capacity, struck out provision authorizing the district court except where express provision therefore was made in a federal statute to deny costs to a plaintiff and in fact impose such costs upon such plaintiff where plaintiff was adjudged to be entitled to recover less than the required amount in controversy, computed without regard to set-off or counterclaim and exclusive of interests and costs, and struck out existing subsection designations.

1976-Subsec. (a). Pub. L. 94–574 struck out $10,000 jurisdictional amount where action is brought against the United States, any agency thereof, or any officer or employee thereof in his official capacity.

28 U.S. Code § 1338(a) – Patents, etc.:

"The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety

protection, copyrights and trademarks. No State court shall have jurisdiction over any claim for relief arising under any Act of Congress relating to patents, plant variety protection, or copyrights."

28 U.S. Code § 1361 - Action to compel an officer of the United States to perform his duty:

"The district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff."

35 U.S. Code § 101 - 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."

35 U.S. Code § 103 - Conditions for patentability; non-obvious subject matter:

"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."

35 U.S. Code § 145 - Civil action to obtain patent:

> "An applicant dissatisfied with the decision of the Patent Trial and Appeal Board in an appeal under section 134(a) may, unless appeal has been taken to the United States Court of Appeals for the Federal Circuit, have remedy by civil action against the Director in the United States District Court for the Eastern District of Virginia if commenced within such time after such decision, not less than sixty days, as the Director appoints. The court may adjudge that such applicant is entitled to receive a patent for his invention, as specified in any of his claims involved in the decision of the Patent Trial and Appeal Board, as the facts in the case may appear and such adjudication shall authorize the Director to issue such patent on compliance with the requirements of law."

Patent Cooperation Treaty:

> The Patent Cooperation Treaty (PCT) is a multilateral Federal treaty on international patent law that was concluded in Washington, D.C. in 1970 and entered in force in 1978. (Patent Cooperation Treaty, Jan. 24, 1978, TIAS 8733, 28 UST 7645.) It is administered by the International Bureau of the World Intellectual Property Organization ("WIPO").
>
> The PCT provides a unified procedure for filing a single patent application (the "international application") to protect an invention, with effect in several countries, instead of filing separate national and/or regional patent applications.

The United States of America is one of the 150 Contracting States, which avow cooperation in the Treaty as follows:

"The Contracting States,

Desiring to make a contribution to the progress of science and technology,

Desiring to perfect the legal protection of inventions,

Desiring to simplify and render more economical the obtaining of protection for inventions where protection is sought in several countries,

Desiring to facilitate and accelerate access by the public to the technical information contained in documents describing new inventions,

Desiring to foster and accelerate the economic development of developing countries through the adoption of measures designed to increase the efficiency of their legal systems, whether national or regional, instituted for the protection of inventions by providing easily accessible information on the availability of technological solutions applicable to their special needs and by facilitating access to the ever-expanding volume of modern technology,

Convinced that cooperation among nations will greatly facilitate the attainment of these aims,

Have concluded the present Treaty."[1]

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[1]wipo.int/export/sites/www/pct/en/texts/pdf/pct.pdf.

Additional material from this filing is available in the Clerk's Office.