No. 18-277

In the Supreme Court of the United States

URVASHI BHAGAT,

Petitioner,

v.

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

Respondent.

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

SUPPLEMENTAL BRIEF TO THE PETITION FOR REHEARING

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SUPPLEMENTAL BRIEF

This supplemental brief to the petition for rehearing is properly restricted in accordance with Supreme Court Rule 15.8 to intervening matter not available at the time of the Petitioner's last filing. Petitioner submits for the Court consideration two apposite opinion editorials and Petitioner's Letter to the President, the Speaker, and the Congress of the United States, calling action on the gravely serious matter of need for innovation in nutrition and its national importance, and obstruction of the same in the present case by the Government by mutilating Title 35 of the United States Code. Each of the papers cited became available after the filing of the Petition for Rehearing and is attached in the appendix hereto.

I. Supplemental Reasons to Grant Certiorari

II. Our Food is Killing Too Many of Us

Dariush Mozaffarian[1], Professor of Nutrition at Tufts University, and Dan Glickman[2], former United States Secretary of Agriculture published an opinion editorial in the New York Times of August 26, 2019[3] (Pet.App.Supp.1a-4a), stressing that **improving American nutrition would make the *biggest* impact on our health care.** The authors assert,

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[1] https://nutrition.tufts.edu/profile/faculty/dariush-mozaffarian
[2] https://en.wikipedia.org/wiki/Dan_Glickman
[3] https://www.nytimes.com/2019/08/26/opinion/food-nutrition-health-care.html

"The Democratic debate on health care has to date centered around who should be covered and who should pay the bill. That debate, which has been going on for decades, has no clear answers and cannot be easily resolved because of two fundamental realities: Health care is expensive, and Americans are sick.

Americans benefit from highly trained personnel, remarkable facilities and access to the newest drugs and technologies. Unless we eliminate some of these benefits, our health care will remain costly. We can trim around the edges — for example, with changes in drug pricing, lower administrative costs, reductions in payments to hospitals and providers, and fewer defensive and unnecessary procedures. These actions may slow the rise in health care spending, but costs will keep rising as the population ages and technology advances.

And Americans are sick — much sicker than many realize. More than 100 million adults — almost half the entire adult population — have pre-diabetes or diabetes. Cardiovascular disease afflicts about 122 million people and causes roughly 840,000 deaths each year, or about 2,300 deaths each day. Three in four adults are overweight or obese. More Americans are sick, in other words, than are healthy.

Instead of debating who should pay for all this, no one is asking the far more simple and imperative question: ***What is making us so sick, and how can we reverse this so we need less health care? The answer is staring us in the face, on average three times a day: our food.***" [Emphasis added]

However, the Petitioner ***has*** asked this question and presented the US Government with the effective inexpensive solution of tailored lipids in its subject US Patent Application no. 12/426,034 and fought for the patent for last 10 years, because without sufficient patent scope the innovation is difficult to implement as explained below and in the Appendices B and C. But the Government has improperly denied the patent, by mutilating Title 35 of the United States Code, and held the implementation of the innovation back for so many years at great public health cost.

III. Public Health is a Mess Because Governments are Obstructing Advancement in Nutrition

In her opinion editorial[4] (Pet.App.Supp.5a-8a) the Petitioner asserts,

> "Experts agree that public health issues are not being solved by the highly trained personnel, remarkable facilities, and access to the newest drugs and technologies, rather health care costs keep rising as the technology advances and that the solution lies in nutrition. Significant part of the problem is that governments favorably grant patents to drugs, devices, and treatments over nutrition, making treatments more financially rewarding over prevention, and increasing the disease burden and health care costs…

[4] Under publisher's review as of printing of this brief. The final publication may be further edited by the editor.

> The misalignment of financial incentives has created a bizarre system where the workforce for the foundation of health, i.e. nutrition is highly unskilled but the healthcare workforce for correcting ill effects of bad nutrition is highly skilled.
>
> The patent system has a vital role in this because the limited exclusivity can provide the higher price point (which will still be a fraction of drug prices) utilizing which the specialized nutritional platform employing a skilled workforce can be developed and implemented. The products can be subsidized for lower income groups in partnership with the governments.
>
> Therefore, ***the foundation of health, i.e. nutrition needs innovation, and governments around the world must support it with protected environment to nurture the innovation***. The result: suffering from diseases and health care spending decreases; productivity, per capita income, and tax income to the governments increases. And we all win!"

IV. Petitioner's Letter to the President, the Speaker, and the Congress of the United States Asserting the Patent System is Obstructing Advancement in Nutrition, Keeping Public on Drugs and Devices, And Promoting the National Disease Burden and Health Care Costs

On August 10, 2019, Petitioner wrote to the President, the Speaker, and the Congress of the United States asserting,

> "The legislature does not restrict patent grant to nutritional innovations, but in practice the patent system disfavors such patent grants, and when nutritional patents are granted, they are severely restricted or dragged in prosecution robbing off proper scope and term for effective implementation, *neutering* the innovation. *Tragically if our innovations were drawn to drug candidates similarly differentiated over prior art, the patents would have been granted many years ago*. Narrow patents in the nutrition arts and favorable patent grant to drugs have created *patent-practice-made humanitarian crises* by perpetuating misinformation, taking us farther away from solving nutritional problems and sustainability, fostering stagnation in the nutrition art, and making us dependent on drugs and devices.
>
> Of note is the disdainful treatment of our patent applications, particularly the application no. 12/426,034 by the US Government and its worldwide effects. We request you to intervene in this *extraordinary case and abrogate the holdings of the USPTO and the Federal Circuit that mutilate Title 35 of the United States Code."*
>
> (Pet.App.Supp. 14a).

The entire Letter to Congress is included in Appendix C (Pet.App.Supp. 9a-72a); the Annexes to the Letter are available online[5]. Petitioner submitted

[5] https://asha-nutrition.com/wp-content/uploads/2019/09/190811LetterToCongress_w_Annexes-compressed.pdf

a similar Petition to the Administrative Council of the European Patent Organization (EPO) and the heads of members states of the EPO, which is also available online[6].

This is a very serious problem where patent offices are copying each other in obstructing advancement in nutrition, while favorably granting patents to drugs and devices, increasing the disease burden and strangling national economies, and perpetuating the problems.

V. Conclusion

Therefore, it is respectfully asserted that the Petition before this Court is directed to matter of national and international importance of proportions never before presented at this Court. Therefore, certiorari is unquestionably warranted for *Bhagat*.

/s/ Burman Y. Mathis
Burman Y. Mathis

Attorney for Petitioner

September 26, 2019

[6] https://asha-nutrition.com/wp-content/uploads/2019/09/190811-Petition-to-EPO-AC-w-Attachments-compressed.pdf

APPENDIX A

Our Food Is Killing Too Many of Us

Improving American nutrition would make the biggest impact on our health care.

By Dariush Mozaffarian and Dan Glickman
Op-ed, The New York Times, Aug 26, 2019

The Democratic debate on health care has to date centered around who should be covered and who should pay the bill. That debate, which has been going on for decades, has no clear answers and cannot be easily resolved because of two fundamental realities: Health care is expensive, and Americans are sick.

Americans benefit from highly trained personnel, remarkable facilities and access to the newest drugs and technologies. Unless we eliminate some of these benefits, our health care will remain costly. We can trim around the edges — for example, with changes in drug pricing, lower administrative costs, reductions in payments to hospitals and providers, and fewer defensive and unnecessary procedures. These actions may slow the rise in health care spending, but costs will keep rising as the population ages and technology advances.

And Americans are sick — much sicker than many realize. More than 100 million adults — almost half the entire adult population — have pre-diabetes or diabetes. Cardiovascular disease afflicts about 122 million people and causes roughly 840,000 deaths each year, or about 2,300 deaths each day. Three in

four adults are overweight or obese. More Americans are sick, in other words, than are healthy.

Instead of debating who should pay for all this, no one is asking the far more simple and imperative question: What is making us so sick, and how can we reverse this so we need less health care? The answer is staring us in the face, on average three times a day: our food.

Poor diet is the leading cause of mortality in the United States, causing more than half a million deaths per year. Just 10 dietary factors are estimated to cause nearly 1,000 deaths every day from heart disease, stroke and diabetes alone. These conditions are dizzyingly expensive. Cardiovascular disease costs $351 billion annually in health care spending and lost productivity, while diabetes costs $327 billion annually. The total economic cost of obesity is estimated at $1.72 trillion per year, or 9.3 percent of gross domestic product.

These human and economic costs are leading drivers of ever-rising health care spending, strangled government budgets, diminished competitiveness of American business and reduced military readiness.

Fortunately, advances in nutrition science and policy now provide a road map for addressing this national nutrition crisis. The “Food Is Medicine” solutions are win-win, promoting better well-being, lower health care costs, greater sustainability, reduced disparities among population groups, improved economic competitiveness and greater national security.

Some simple, measurable improvements can be made in several health and related areas. For example, Medicare, Medicaid, private insurers and hospitals should include nutrition in any electronic health record; update medical training, licensing and continuing education guidelines to put an emphasis on nutrition; offer patient prescription programs for healthy produce; and, for the sickest patients, cover home-delivered, medically tailored meals. Just the last action, for example, can save a net $9,000 in health care costs per patient per year.

Taxes on sugary beverages and junk food can be paired with subsidies on protective foods like fruits, nuts, vegetables, beans, plant oils, whole grains, yogurt and fish. Emphasizing protective foods represents an important positive message for the public and food industry that celebrates and rewards good nutrition. Levels of harmful additives like sodium, added sugar and trans fat can be lowered through voluntary industry targets or regulatory safety standards.

Nutrition standards in schools, which have improved the quality of school meals by 41 percent, should be strengthened; the national Fresh Fruit and Vegetable Program should be extended beyond elementary schools to middle and high schools; and school garden programs should be expanded. And the Supplemental Nutrition Assistance Program, which supports grocery purchases for nearly one in eight Americans, should be leveraged to help improve diet quality and health.

The private sector can also play a key role. Changes in shareholder criteria (e.g., B-Corps, in which a

corporation can balance profit versus purpose with high social and environmental standards) and new investor coalitions should financially reward companies for tackling obesity, diabetes and other diet-related illness. Public-private partnerships should emphasize research and development on best agricultural and food-processing practices. All work sites should demand healthy food when negotiating with cafeteria vendors and include incentives for healthy eating in their wellness benefits.

APPENDIX B

Public Health is a Mess Because Governments are Obstructing Advancement in Nutrition

Nutrition businesses need major innovation that can only come with realignment of financial incentives, such as limited exclusivity granted by patents, but governments around the world are obstructing innovation in nutrition.

By Urvashi Bhagat

Ms. Urvashi Bhagat is the President and CEO of Asha Nutrition Sciences, Inc.

(Submitted for publication on September 24, 2019)

Experts agree that public health issues are not being solved by the highly trained personnel, remarkable facilities, and access to the newest drugs and technologies, rather health care costs keep rising as the technology advances and that the solution lies in nutrition. Significant part of the problem is that governments favorably grant patents to drugs, devices, and treatments over nutrition, making treatments more financially rewarding over prevention, and increasing the disease burden and health care costs.

Though there is no restriction in patent laws, in practice the patent system favors patent grants to drugs, devices, and treatments over patent grant to nutritional solutions. Further, when nutritional

patents are granted, they are severely restricted, such as to a narrow formulation or to fortification of foods with certain nutrients for certain use.

US and Europe are bellwether patent offices, each of which has developed their own methods of obstructing innovation in nutrition. The holdings of these two offices are copied by other patent offices around the world. In effect, governments around world in collusion are obstructing innovation in nutrition.

This is creating chaos in nutrition, because as opposed to drug companies, which rely upon high margins for success afforded by clear exclusivity from patents, food businesses rely upon volumes for success because the restricted patents rarely give them sufficient margins.

In order to drive volumes, food businesses put out thousands of food products with their own spin on why their products are healthy, bombarding citizens with contradicting marketing messages making it more difficult for them to practice good nutrition.

As it is nutrition is exceptionally complex. It involves infinite number of interacting nutrients, that affect our bodies in infinite number of ways, including which genes are expressed and which ones are silenced. Further, some nutrients are potent in micrograms and extremely difficult to monitor. Furthermore, nutrients in food sources are highly unpredictable, based on geography, cultivation, and storage. The problem is not so much the amount of food consumed, but the components of food and how it is prepared, which influences cravings and how

much is consumed. Above all that, nutrition has a delayed effect, in that it can take a decade or more for cause and effect to be known.

For example, take lipids, fatty acids like omega-6 and omega-3, and certain vitamins and phytochemicals. Scientists have taken decades to understand lipids and gone back and forth on their guidance on lipids and businesses have peddled thousands of lipid supplements thoroughly confusing the citizens. How do we expect citizens to understand and follow?

Therefore, general public cannot self-configure nutrition and the governments and food businesses make it harder for them, which reflects in the diet-related incidence of disease.

The solution is in tailoring nutrition for public by age, gender, diet-type, and medical disposition, it is not in randomly fortifying products or selling thousands of "healthy" products, which create excesses and imbalances.

Tailored lipids alone are an inexpensive innovative solution to a large part of the problem, since imbalanced lipid intake is associated with almost all chronic diseases and hormonal issues. Americans affected include: 90 million from diabetes and pre-diabetes, 1.6 million annual cancer diagnoses, 54.4 million from arthritis, and 26 million from asthma; and hormonal imbalances of which 80% of women suffer.

But tailoring nutrition requires immense capital. For example, food businesses that typically employ unskilled workforce—think of all the restaurant

workers with minimal education—will have to hire highly skilled workforce despite thin margins, and these specialized food tailoring businesses will not be able to rely upon volumes for viability. It is difficult to attract investment in such a scenario.

The misalignment of financial incentives has created a bizarre system where the workforce for the foundation of health, i.e. nutrition is highly unskilled but the healthcare workforce for correcting ill effects of bad nutrition is highly skilled.

The patent system has a vital role in this because the limited exclusivity can provide the higher price point (which will still be a fraction of drug prices) utilizing which the specialized nutritional platform employing a skilled workforce can be developed and implemented. The products can be subsidized for lower income groups in partnership with the governments.

Therefore, the foundation of health, i.e. nutrition needs innovation, and governments around the world must support it with protected environment to nurture the innovation. The result: suffering from diseases and health care spending decreases; productivity, per capita income, and tax income to the governments increases. And we all win!

APPENDIX C

August 10, 2019 **BY EMAIL**

SUBJECT:
PATENT SYSTEM IS OBSTRUCTING ADVANCEMENT IN NUTRITION, KEEPING PUBLIC ON DRUGS AND DEVICES, AND PROMOTING THE NATIONAL DISEASE BURDEN AND HEALTH CARE COSTS

The President
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

The Honorable Nancy Pelosi
Speaker, United States House of Representatives
1236 Longworth House Office Building
Washington, DC 20515

The Honorable Lindsey Graham
Chairman, Committee on the Judiciary
United States Senate
290 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Lamar Alexander
Chairman, Committee on Health, Education,
Labor & Pensions
United States Senate
455 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Jerrold Nadler
Chairman, Committee on the Judiciary

United States House of Representatives
2132 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Frank Pallone
Chairman, Committee on Energy and Commerce
United States House of Representatives
2107 Rayburn House Office Building
Washington, DC20515

The Honorable Dianne Feinstein
Ranking Member, Committee on the Judiciary
United States Senate
331 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Patty Murray
Ranking Member, Committee on Health, Education, Labor & Pensions
United States Senate
154 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Doug Collins
Ranking Member, Committee on the Judiciary
United States House of Representatives
1504 Longworth House Office Building
Washington, D.C. 20515

The Honorable Greg Walden
Ranking Member, Committee on Energy and Commerce
United States House of Representatives
2185 Rayburn House Office Building
Washington, DC 20515

The Honorable Thom Tillis
Chairman, Subcommittee on Intellectual Property

United States Senate
113 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Henry C. Johnson
Chairman, Subcommittee on Courts,
Intellectual Property, and the Internet
United States House of Representatives
2240 Rayburn House Office Building
Washington, DC 20515

The Honorable Ben Sasse
Chairman, Subcommittee on Oversight,
Agency Action, Federal Rights and Federal Courts
United States Senate
107 Russell Senate Office Building
Washington, DC 20510

The Honorable Martha Roby
Ranking Member, Subcommittee on Courts,
Intellectual Property, and Internet
United States House of Representatives
504 Cannon House Office Building
Washington, DC 20515

The Honorable Michael B. Enzi
Chairman, Subcommittee on Primary Health
and Retirement Security
United States Senate
379A Senate Russell Office Building
Washington, DC 20510

The Honorable Christopher Coons
Ranking member, Subcommittee on Intellectual Property
United States Senate
218 Russell Senate Office Building
Washington, DC 20510

The Honorable Richard Blumenthal
Ranking member, Subcommittee on Oversight,
Agency Action, Federal Rights and Federal Courts
United States Senate
706 Hart Senate Office Bldg.
Washington, DC, 20510

The Honorable Bernie Sanders
Ranking Member, Subcommittee on
Primary Health and Retirement Security
United States Senate
332 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Anna Eshoo
Chairwoman Subcommittee on Health
United States House of Representatives
202 Cannon House Office Building
Washington, DC 20515

cc.

The Honorable Wilbur Ross
Secretary of Commerce
U.S. Department of Commerce
1401 Constitution Ave NW
Washington, DC 20230

The Honorable Andre Iancu
Director,
United States Patent and
Trademark Office
Madison Building
600 Dulany Street
Alexandria, VA 22314

Subject Recap:
Patent System is Obstructing Advancement in Nutrition, Keeping Public on Drugs and Devices, and Promoting the National Disease Burden and Health Care Costs

Case in Point:
The Disdainful Treatment of Asha Nutrition Sciences' Patent Applications (12/426,034 (pending since 2009), 13/332,251 (granted after 8 years of pendency), and 13/877,847 (pending since 2013)) by the United States Patent and Trademark Office, and the United States Court of Appeals for the Federal Circuit, and The Worldwide Consequences of the Same

Dear Mr. President, Madam Speaker, Honorable Congress Members:

We the public and the United States Government have rallied, caucused, campaigned, complained, and grumbled about our over $3 trillion annual healthcare costs and associated social burden. Rather it is a national obsession to lament about the health care system. Yet when our small company, Asha Nutrition Sciences, in 2008 presented the Government (USPTO) with an innovative inexpensive solution to significantly solve the problem at the base via tailored lipid nutrition (a fitting complement to Government sponsored healthcare), it was snubbed by the Government (USPTO, the US Court of Appeals for the Federal Circuit, and the US Supreme Court) rather

apathetically, and the Government declined to grant us proper and timely patent rights to properly nurture the innovation to bring about leaps of advancement for future generations.

The legislature does not restrict patent grant to nutritional innovations, but in practice the patent system disfavors such patent grants, and when nutritional patents are granted, they are severely restricted or dragged in prosecution robbing off proper scope and term for effective implementation, *neutering* the innovation. *Tragically if our innovations were drawn to drug candidates similarly differentiated over prior art, the patents would have been granted many years ago*. Narrow patents in the nutrition arts and favorable patent grant to drugs have created *patent-practice-made humanitarian crises* by perpetuating misinformation, taking us farther away from solving nutritional problems and sustainability, fostering stagnation in the nutrition art, and making us dependent on drugs and devices.

Of note is the disdainful treatment of our patent applications, particularly the application no. 12/426,034 by the US Government and its worldwide effects. We request you to intervene in this *extraordinary case and abrogate the holdings of the USPTO and the Federal Circuit that mutilate Title 35 of the United States Code*.

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Annex B: Cited art "Olive oil" webpages from http://nutritiondata.self.com/facts/fats-and-oils/509/2 (accessed February 11, 2015)

Annex C: Cited art "Walnut oil" webpages from http://nutritiondata.self.com/facts/fats-and-oils/589/2 (accessed February 11, 2015)

Annex D: Cited art "Olives" and "Olives Nutrient Analysis" from www.whfoods.com webpages http://web.archive.org/web/20060314112112/http://www.whfoods.com/genpage.php?pfriendly=1&tname=foodspice&dbid=46 (published: March 14, 2006) and http://web.archive.org/web/20060314112106/http://www.whfoods.com/genpage.php?tname=nutrientprofile&dbid=111 (published: March14, 2006)

Annex E: Cited art "Walnuts" and "Walnut Nutrient Analysis" from www.whfoods.com webpages http://web.archive.org/web/20061109210019/http://www.whfoods.com/genpage.php?tname=foodspice&dbid=99 (published: November 9, 2006) and http://web.archive.org/web/20061109221127/http://ww

[1] Almost all the references/publication cited in this paper are on record at USPTO and have been submitted to the Federal Circuit, with the exception of petitions and briefs submitted to the Supreme Court, which were added to the record at the USPTO but not at the Federal Circuit. For the sake of brevity, only a subset of documents from the Joint Appendix submitted to the Federal Circuit is included here, additional documents are available upon request.

w.whfoods.com/genpage.php?tname=nutrientprofile&dbid=132 (published: November 9, 2006)

Annex F: Mark et al., U.S. Patent No. 5,549,905 https://patentimages.storage.googleapis.com/d4/c9/82/05d9c5fa9238b2/US5549905.pdf

Annex G: Decision of the Patent Trial and Appeal Board at USPTO, dispatched on April 15, 2016

Annex H: Annotated Opinion of the United States Court of Appeals for the Federal Circuit dated March 16, 2018

Annex I: Petition for Panel Rehearing and Rehearing En Banc to US Court of Appeals for the Federal Circuit of April 25, 2018

Annex J: Open Letter to Andrei Iancu, Director, USPTO, and Sharon Prost, Chief Judge, Federal Circuit, April 27, 2018

Annex K: Petition for a Writ of Certiorari to the US Supreme Court, August 29, 2018 (case no. 18-277)

Annex L: Amicus Brief in Support of Petition for a Writ of Certiorari (case no. 18-277), October 5, 2018

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Annex X: Kent L. Erickson Testimony, July 14, 2015

Annex Y: Bhagat U. Das UN., Arch Med Sci 2015; 11, 4: 807–818

Annex Z: Simopoulos et al., Ann Nutr Metab 1999;43:127–130.

Annex AA: Lands WE. Ann. N.Y. Acad. Sci. 1055:179–192 (2005)

Annex AB: The World's Healthiest Foods (WHFoods.com) The George Mateljan Foundation (non-profit) "*A New Way of Looking at Proteins, Fats and Carbohydrates*" published January 2007. http://web.archive.org/web/20070104020351/http:/whfoods.com/genpage.php?tname=faq&dbid=7#polyun

Annex AC: "Omega-6 fatty acid" Wikipedia, accessed March 5, 2018

Annex AD: Petition to the Administrative Council of the European Patent Organization, August 10, 2019

I. Prosecution Summary of the '034 Application

Application no. 12/426,034 (the '034 application (Annex A)) was filed on April 17, 2009 and has April 2008 priority. The inventions pertain to tailored delivery of dosages of omega-6 fatty acids relative to other lipids (fatty acids, antioxidants, and phytochemicals), because of continuing *mass miseducation in the art that omega-6 fatty acids are unhealthy* and that intake and activity of omega-6 should be suppressed using other nutrients, and grave consequences of this mass miseducation on public health.

Due to its bias against nutrition the USPTO issued a dozen improper rejections, citing remotely related art as anticipatory under 35 USC § 102 and applying obviousness rejections under 35 USC § 103 despite opposite teachings in the prior art. None of the rejections could not be sustained. The obviousness rejections were particularly improper since the '034 Application itself evidences that the subject matter is poorly understood, that there are opposite teachings in the prior art, and that the long-felt critical public health need remains unmet (e.g., see Annex A paragraphs [0006]-[0007]). Furthermore, even the art cited by the USPTO teaches the opposite of the claimed subject matter (discussed below).

However, then the USPTO resorted to *excising limitations* from the claims, *mutilating* the law, and *reconstructing* the prior art and products of nature to allege anticipation by nature under § 101—applied for the first time in *7th* Office Action in October 2013.

The Examiner issued final rejection on September 22, 2015, ***rejecting all 55 claims[2] under § 101*** over alleged anticipation by *alleged* "products of nature", *individual oils*, olive oil (Annex B) and walnut oil (Annex C), each separately, and ***rejecting 52 claims (except Claims 102, 107, and 119) under § 102*** over alleged anticipation by *individual fruits/nuts*, olives (Annex D) and walnuts (Annex E), each separately.

Some claims were also rejected over alleged anticipation by U.S. Patent No. 5,549,905 ("Mark") (Annex F). Applicant[3] submitted reams of arguments and evidence including skilled person's testimony that Mark does not anticipate, however, Mark is not dispositive in any case since most claims (e.g. independent Claim 91 and dependent claims, and dependent claim 82 which can replace claim 65) are not rejected under Mark.

Patent Trial and Appeal Board affirmed Examiner's rejections on April 15, 2016 (Annex G) and denied Rehearing on June 21, 2016.

Independent Claim 65 rejected under § 101 (allegedly anticipated by olive oil) and under § 102 (allegedly anticipated by olives) recites:

> 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

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[2] See full claim chapter of the rejected claims at the end of Annex A.

[3] "Applicant" refers to Asha Nutrition Sciences, the assignee of the application, and "inventor" and "I" refers to Urvashi Bhagat, the undersigned throughout this paper.

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 not more than 40 grams.

Dependent Claim 102 *solely* rejected under § 101 (i.e., not anticipated by any product of nature, including olives or walnuts or their oils but allegedly still a product of nature because it is obtained by mixing naturally occurring omega-6, omega-3, and omega-9 fatty acids) recites:

The formulation of claim 65, wherein the dosage of total fat is 10-100 grams, the dosage of omega-6 fatty acids is from 1 to 40 grams; the dosage of omega-3 fatty acids is from 0.1 to 5 grams, the ratio of monounsaturated fatty acids to polyunsaturated fatty acids is in the range of 1:1 to 3:1, the ratio of monounsaturated fatty acids to saturated fatty acids is 1:1 to 5:1, the ratio of omega-9 to omega-6 fatty acids is in the range of 1:1-3:1, and the ratio of omega-6 to omega-3 fatty acids is in the range of 4:1 to 45:1.

Independent Claim 91 rejected under § 101 (allegedly anticipated by walnut oil) and under § 102 (allegedly anticipated by walnuts) recites:

A lipid-containing formulation, comprising a dosage of omega-6 fatty acids, wherein the

> omega-6 fatty acids are greater than 20% by weight of the total lipids, 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, the formulation comprising polyunsaturated, monounsaturated, and saturated fatty acids, and wherein the formulation includes at least
>
> (i) one or more polyunsaturated fatty acids selected from [omitted], and
>
> (ii)nutrients including at least
>
> (a) one or more polyphenols, or
> (b) one or more phytochemicals,
> the one or more phytochemicals being selected from [omitted].

Thus, USPTO obstructed *critical innovation* directed to specific *formulations* comprising *intermixtures in casings* and *dosages of lipids*—*that is "composition of matter" and "manufacture" and "process*"—over individual foods contrary to 35 USC § 101. Critical does not mean unpatentable or "product of nature;" further, nature being highly unpredictable in nutrient (lipid) content is incapable of providing "dosage" of anything, let alone tailor it for subjects (discussed below).

Further, § 102 was applied though *identical* invention as claimed is not disclosed and enabled in either of olives, walnuts, or their oils, or Mark, and a competitor could *not* obtain the claimed subject matter from the prior art and that the prior art does *not necessarily* function as claimed. Congress

created § 103 in the 1952 Patent Act for such rejections, but USPTO applied the rejections under § 102 because § 103 rejections could not be sustained due to unexpected results and opposite teachings in the prior art, i.e. USPTO circumvented the law. The impropriety of the rejections is discussed further in Sections III.5 and IV.1-2.

United States Court of Appeals for the Federal Circuit rubberstamped USPTO on March 16, 2018, contrary to Title 35 USC and a large body of its own and Supreme Court precedents without a meaningful review, as required by Administrative Procedure Act, issuing a non-precedential opinion (Annex H) so as to not affect the case law ***singling out this case for injustice***, and denied the Petition for Rehearing and Hearing En Banc (Annex I) on June 1, 2018, heedless to the Amicus Brief submitted on May 9, 2018, and despite the opinions of well-known patent lawyers that the case was improperly decided (see Addendums to Annex I). Applicant submitted an Open Letter to Director Andrei Iancu at USPTO and Chief Judge Sharon Prost at the Federal Circuit, on April 27, 2018 asserting that USPTO's and the Federal Circuit's actions were improper (Annex J).

Petition for a Writ of Certiorari was submitted to the Supreme Court of the United States on August 29, 2018 (Annex K) (case no. 18-277) supported with an amicus brief submitted on October 5, 2018 (Annex L), and a Supplemental Brief on October 22, 2018 (Annex M). The Supreme Court denied the acceptance of the amicus brief for being one day late and the Petition on October 29, 2018.

In view of extreme abuse of discretion in examination and appeal review, Petition for a Writ of Mandamus was submitted to the Supreme Court on March 30, 2019 (Annex N) (case no. 18-1274). An amicus brief was submitted on May 3, 2019 (Annex O). The Supreme Court denied the Petition on May 13, 2019. Petition for Rehearing for Writ of Mandamus was submitted on June 7, 2019 (Annex P), which was denied on July 15, 2019.

In view of intervening circumstances in the form of the US Senate's recently-published proposed language to reform Title 35 U.S.C. § 101 based on problematic behavior of the USPTO and the lower courts[4], Petition for Rehearing for the Writ of Certiorari (case no. 18-277) was submitted to the Supreme Court on July 11, 2019 (Annex Q), which is currently pending.

II. The Claimed Inexpensive Innovative Solution—*Formulations of Tailored Lipid Dosages!*

The claimed inexpensive innovative solution is *formulations of tailored lipid dosages*, particularly of omega-6 fatty acids—**more critical for health than milk at any age** and **more crucial for protecting and enhancing public health than the most effective healthcare plan**, whether we call it "universal health care", "Medicare for all", or by any other name, particularly in view of the mass chaos in the art.

Chronic diseases and preventable medical conditions cost about $3.7 trillion annually in the

[4] https://www.tillis.senate.gov/services/files/E8ED2188-DC15-4876-8F51-A03CF4A63E26

United States[5]. Almost all chronic diseases are associated with improper intake of lipids (fatty acids, certain vitamins like A, E, D, K, and certain phytochemicals like sterols and polyphenols) evidenced by 100s of studies conducted in past 100 years[6]. This is because lipids are crucial components of cell membranes in animal body and play critical role in many physiological functions. For example, they are involved in gene regulation, and their derivatives are important hormones and biological messengers, affecting functions such as blood vessel dilation, platelets aggregation, pain modulation, inflammation, and cell growth. Therefore, when lipid intake is corrected by delivery of tailored lipid dosages by subject type, the foundation of health is corrected, hormonal balance is corrected, and immunity is strengthened and susceptibility to infections is reduced.

Therefore, ***the claimed inventions can substantially reduce the suffering of 117 million Americans from chronic diseases and of 80% of women from hormonal issues*** and ***can complement Government sponsored healthcare.***

Americans are literally put under a knife in cardiovascular surgery and subjected to drugs and devices (treatments) in diabetes, because ***treatments are made more financially rewarding by***

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[5] Milken Institute, **"**The Cost of Chronic Disease in the U.S.," May 2018.

[6] E.g., see Baum et al.*, "Fatty acids in cardiovascular health and disease: A comprehensive update"* Journal of Clinical Lipidology (2012) 6, 216–234; Bhagat U. Das UN. "*Potential role of dietary lipids in the prophylaxis of some clinical conditions"* Arch Med Sci 2015; 11, 4: 807–818 (Annex Y).

preferentially giving them patents/exclusive markets, and ***preventative solutions such as claimed tailored lipid dosages are denied patent protection and therefore effective implementation***. For example, why are we throwing medications on people who have mild depression or on young women suffering from premenstrual syndrome, which can be significantly abated with correct lipid delivery? Same with,

- 90 million people suffering from diabetes or pre-diabetes,
- 54 million people with arthritis,
- 26 million people with asthma, and so on...

If a business is paid $10,000 or like for treatments favored by the patent system, why would they provide lipid dosages for $100 or like? It is basic economics!

However, when preventative solutions such as tailored lipid dosages are given patent protection, the limited exclusivity allows higher product margins and a protected period to recover investment in the required novel infrastructure for the novel product platform.

Ultimately, we all win by implementing such critical preventative solutions:

- when prevention is in full gear, we can reallocate resources (currently usurped in treatment) to find cure to ailments that cannot be prevented, potentially benefiting "treatment businesses";

- reduction in suffering from disease increases productivity and per capita income;
- reduction in suffering from disease increases productivity and Gross Domestic Product; and
- reduction in suffering from disease increases productivity and per capita income and in turn increases taxes earned by the Government.

Patents for Humanity Application was submitted to USPTO on November 8, 2015 (Annex R) asserting the importance of the innovation particularly for the impoverished populations. Additionally, *eleven* testimonies from esteemed scientists are on record testifying that the claimed solutions are extremely important for public health (a subset of which is included as Annexes S-X).

In his testimony of September 29, 2014 (Annex U), Dr. Rustagi testified:

> *"Thus, the art recognized in 1929 that the problem existed as noted in paragraph [0019]. However, the art has failed to solve the long-felt, critical and unmet need until the April 2008 priority date of the subject patent application, i.e. for ~80 years. There have been many persistent attempts as evidenced by the references cited above (e.g. Mark et al., whfoods.com, Lands 1986 and 2005; Simopoulos 1999; Hamazaki et al., 2003 supra), but the problem has not been solved. Lipid art has been struggling to find what are the right combinations of omega-6 and omega-3 and other lipids for consumption, how to keep the fatty acids stable on shelf (without formation of toxic compounds) but bio-available in-vivo (Chen and Chaiyasit supra). Inventions of instant*

claims 65, 91, 98, 122, 129, and 130 have devised the solutions. Thus, the invention of the subject patent application solves a long-felt critical persistent unmet need, and has great potential to protect and improve public health." See para [0019]-[0023].

*"[The technologies]… are well-reasoned and directed at much needed lipid solutions, particularly in light of mass erroneous teachings and confusion in the lipid art."*See para [0026]."

Drs. Robert Rucker and Undurti Das have given similar testimony, which is on record at USPTO and was submitted to the Federal Circuit in the Joint Appendix.

III. Why Are Tailored Lipid Dosages Not Implemented Given the Momentous National Importance?

It is self-evident from our daily lives and the prosecution history at USPTO (discussed above and below) that the innovation described above has not been implemented despite the momentous national implications.

The reasons include:

1. Certain aspects of the science are not well understood.
2. Misconception that teaching and publication of tables listing lipid content in common foods is sufficient.
3. Tailored lipid dosages are difficult to implement.

4. Tailored lipid dosages are economically infeasible business without sufficient patent scope.
5. The patent system disfavors proper patent grant to nutritional solutions
6. Special interest groups including the patent system thwart preventative efforts.

Each of the above points is further elaborated below.

1. Certain Aspects of the Science are Not Well Understood

There is mass misinformation both in the popular and scientific media as to what constitutes proper lipid intake.

Prior to 2008 (the priority date of '034 application) scientists understood that lipids are important for health, but they failed to understand the relative importance of various lipid classes and total lipid intake. For example, prior to 2008, scientists overwhelmingly taught to reduce intake of omega-6 family of fatty acids and increase the intake of omega-3 family of fatty acids, because omega-6 was widely believed to cause inflammation and numerous diseases and omega-3 was believed to be anti-inflammatory and counter the effects omega-6[7]. Prior to 2008, low omega-6 to omega-3 ratios like 1:1 or 2:1 were widely taught and very low dosages, for

[7] Simopoulos et al., "Essentiality of and Recommended Dietary Intakes for Omega-6 and Omega-3 Fatty Acids" Ann Nutr Metab 1999;43:127–130 (Annex Z).

example *less than 1g* (less than 1% of calories) were taught[8]. Moreover, whenever prior art found another nutrient that inhibited the activity of omega-6 fatty acids, they recommended increased intake of such a nutrient[9].

Such teachings were reported in numerous scientific publications, numerous patents were issued to high omega-3 containing formulations and methods of treatment[10], and many mainstream publications advocated high use of omega-3[11]. Many companies marketed and profited from such products containing high amounts of omega-3. For example, Lovaza (omega-3) was marketed by Reliant Pharmaceuticals (sold to GlaxoSmithKline for $1.6 billion in 2007).

In early 2000s, motivated by my own mother's suffering from neural disease and premature death, I investigated the effect of relative intake of various lipids in live subjects and was astonished to find that such a large body of scientists had been incorrect and

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[8] *Lands WE. "Dietary Fat and Health: The Evidence and the Politics of Prevention"* Ann. N.Y. Acad. Sci. 1055: 179–192 (2005), (page 183, para 4) (Annex AA).

[9] Wu D. et al., Am J Physiol Cell Physiol 275:661-668, 1998; Shah et al., Biochemical Pharmacology, Vol. 58, pp. 1167–1172, 1999; O'Leary et al., Mutation Research 551 (2004) 245–254.

[10] US Patent 7759507 (Jul 2010), teaching "omega-6 to omega-3 LCPUFAs of about 0.25:1 to about 3:1" (col 3).

[11] "*A New Way of Looking at Proteins, Fats and Carbohydrates*" http://web.archive.org/web/20070104020351/http:/whfoods.com/genpage.php?tname=faq&dbid=7#polyun mainstream public education website, The World's Healthiest Foods (WHFoods.com), run by The George Mateljan Foundation (non-profit) teaching, "ideal ratio of omega-3 to omega-6…is estimated to be around 1:2" (Annex AB).

that they had endangered public health at such a large scale[12]. I found dosage of omega-6 to be most important for health, dependent on age, gender, bodyweight (e.g., greater than 5% of calories, noting that % of calories is not synonymous with dosage) and that omega-3 requirement for health was very low and its benefits were ephemeral, that long-term effects of fatty acids were different from short-term, that ratios of omega-6 to omega-3 should be at least 4:1 and could be very high such as 50:1, that the dosage was the most important factor. For example, if we kept the dosage of omega-6 for an adult female below 20g/day, the ratio became less relevant, but that high relative amounts of omega-3 interfered with omega-6 actions. I also found that initial increase in omega-6 from deficient state caused unfavorable symptoms but that health improved after the body adjusted to higher dosage of omega-6.[13] This explained the prior art had failed to understand the dose-effect of omega-6.

Understanding the dose-effect was an important finding, which the prior art had failed to understand. The prior art held that there was a proportional increase in adverse health with step-wise increase in omega-6 in the range of 0.5 to 4.4% of calories[14], therefore "ingestion of about 1 percent of daily

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[12] Bhagat U, "*Denying Patents on Applications of Discoveries Puts Public Health at Risk*" published online at https://www.ipwatchdog.com/2018/10/04/denying-patents-discoveries-puts-public-health-risk/id=101994 October 4, 2018 (Annex M)

[13] The'034 Application, Examples 11-27 (Annex A).

[14] *Ip et al.,* "*Requirement of Essential Fatty Acid for Mammary Tumorigenesis in the Rat*"; Cancer Research 45, 1997-2001, May 1985.

calories" or even "0.5-1.0% of calories"—0.9-1.9g/day based on 1700-calorie diet—met the omega-6 requirements[15].

However, my experiments demonstrated that omega-6 greater than 11g/day (for adults) was required to overcome adverse health, and that the deficiency of omega-6 potentiates certain mechanisms, such that sudden increases in omega-6 have an overflow effect which can lead to myocardial infarction, strokes, infections, and physiological disturbances[16]. Later publications corroborated my findings.[17]

Thus, prior art was motivated to reduce subject's omega-6 intake because increases in omega-6 produced undesirable health effects. Skilled persons could not predict that higher levels of omega-6 fatty acids would produce desirable health effects, therefore, skilled person in prior art could not determine and practice the suitable dosages of omega-6 and omega-3 fatty acids for a subject taught in the subject applications.

I also found high amounts of omega-9 (monounsaturated fatty acids) to lead to adverse health, and phytochemicals and antioxidants to increase requirement for omega-6 and reduce requirements/tolerance for omega-3.

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[15] Lands, Nutrition Reviews 1986:44-6:189-95; and Lands WE. "Dietary Fat and Health: The Evidence and the Politics of Prevention" Ann. N.Y. Acad. Sci. 1055: 179–192 (2005)
[16] The'034 Application, Examples 11-27 (Annex A).
[17] Lu et al., Lipids in Health and Disease 2010:9:106.

These discoveries were momentous because they set the stage for many more discoveries. Based on my discoveries I filed for patents in April 2008. The discoveries are explained in the above referenced applications (e.g., Annex A). The subject applications are intentionally written in layperson terms to raise awareness among the general public.

In his testimony of October 7, 2012 (Annex S), Dr. Erickson testified:

> *"The subject application contains very important focal points that were not understood prior to this disclosure. Most important of those as discussed above is that the prior art failed to fully understand the importance of omega-6 for health. Human and animal tissue contains many times omega-6 as compared to omega-3. Omega-3 can be preferentially metabolized. However, omega-6 has a shorter in-vivo life, possibly due to myriad of critical metabolites for which it is a precursor. Therefore, a lot more omega-6 is usually required as compared to omega-3. This disclosure indicates that deficiency of omega-6 is a greater problem. The disclosure focuses on the fact that certain nutrients including antioxidants and phytochemicals can effectively enhance omega-3 bioactivity in-vivo but inhibit the metabolism of omega-6. The risks of sudden increase of omega-6 or withdrawal of omega-3 have been explained, which was not previously appreciated or incorporated into dietary strategy. Prior dogma held that omega-6 causes disease, whereas this disclosure explains that the deficiency of omega-6 potentiates certain mechanisms, such that sudden increases in omega-6 have an overflow*

effect which can lead to myocardial infarction, strokes, infections, and physiological disturbances. Several examples have been given to manage menopause, sleep disorders, neural disease, mental function, musculoskeletal disorders, obesity, diabetes, digestive, reproductive, pulmonary, ophthalmologic, dermatologic, and immune functions. These are multiple significant discoveries. Novel methods of treatment, administration, use, and tailored preparation are also disclosed. Because omega-6 and omega-3 significantly impact the structure and function of multiple physiological processes, correct delivery has a beneficial effect on many diseases. Sufficient directions are provided for the practitioner in the disclosure." Para [0023].

Subsequent to April 2008 priority date of the subject application the state of the art started to change. American Heart Association issued an advisory in 2009 to correct the perception that omega-6 are unhealthy[18]. In 2010, the US Department of Health and Human Services increased the recommended omega-6 intake in its Dietary Guidelines for Americans. Yet they did not teach all features in our applications and claims. Further, teaching is not sufficient as explained below.

2. Misconception That Teaching and Publication of Tables Listing Lipids in Foods Is Sufficient

[18] Harris *et al.*, *Circulation* 200, 119:902-907.

Though the disclosure in our applications can be followed by general public, it is extremely difficult for public to obtain suitable dosages of lipids.

First, the public continues to be *misled* to believe that foods come with set nutrient (lipid) content as published in various tables listing nutrients in foods, such as olives and walnuts in Annexes B-E. In reality, nutrient content in foods varies based on genetics and epigenetics, and cultivating conditions, such as soil used, fertilizer used, hours of sunlight, and water composition, and from production batch to batch[19]. For example, olives have been found to have 3.5-21% omega-6 fatty acids content,[20] walnuts similarly vary in lipid content[21]. Therefore, all the published nutrient tables are giving us is nutrient content in the *tested batch* of the type of food, such as olives or walnuts.

Second, less than 1% of public can even name lipids—in a survey less than 1% of Americans correctly named six fats considered to be solid.[22] How can we expect them to consider minor lipids such as vitamins like A, E, D, K, sterols, and polyphenols present in foods that are potent in

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[19] Erickson testimony, January 31, 2014, para [003] (Annex T).
[20] The Olive Oil Source, https://www.oliveoilsource.com/page/chemical-characteristics#Fatty
[21] Tsao et al., "Fatty Acid Profiles, Tocopherol Contents, and Antioxidant Activities of Heartnut (Juglans ailanthifolia Var. cordiformis) and Persian Walnut (Juglans regia L.)" J. Agric. Food Chem. 2007, 55, 1164-1169.
[22] International Food Information Council Foundation, 2011 Food & Health Survey.

micrograms[23], particularly from oils because they are absorbed differently than whole foods?

Finally, it is too complex for the public to formulate lipid dosages for different family members on a daily basis.[24]

3. Tailored Lipid Dosages are Difficult to Implement

Tailored lipid dosages are difficult to implement because of the points made above in Section III.2. For example, how to tailor lipid dosages despite unpredictability in food sources, how to control dosages of minor lipids such as vitamins like A, E, D, K, sterols, and polyphenols, how to create a spectrum of products keeping total lipid intake in check, giving consumers a regimen but with variations to maintain flexibility and gastronomic appeal, and how to make it work in daily life?

The complexity of the products necessitates a novel commercial structure under the direction of skilled persons.

4. *Tailored Lipid Dosages are Economically Infeasible Business Without Sufficient Patent Scope*

The complexities described in Sections III.2 and III.3 in formulating and implementing tailored lipids dosages make implementing these solutions economically infeasible without sufficient patent

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[23] Tsao et al., supra.
[24] Bhagat and Das (Annex Y).

scope. The profit margins in food products are too thin to support recovery of investment in specialized products *necessitating* novel infrastructure and public teaching to *rise above the noise* created by 1000s of oils, oil mixtures, nut mixtures, and supplements on the market.

However, when the innovative tailored lipid dosages are given sufficient patent protection, the limited exclusivity allows marketing the products at higher margins, making it feasible to invest in the novel infrastructure and public teaching.

5. The Patent System Disfavors Proper Patent Grant to Nutritional Solutions

There is a most definite bias against nutrition in the patent system evidenced by the prosecution history of the '034 Application at USPTO, the appeal review at the Federal Circuit, and the refusal of the Supreme Court to accept the petitions for review despite clear violations of the law and abuse of discretion.

USPTO's unwillingness to grant proper patent protection to nutrition solutions is evidenced by the following in the subject applications:

1. Despite the fact that claims were drawn to linking features—dosages fatty acids for ingestion by a subject—numerous restrictions were placed on the claimed subject matter forcing divisional application filing.[25]

[25] USPA 12/426,034 Office action dated October 14, 2010, p. 2.

2. Alleged that claims are not patentable being drawn to recipes[26], though they are drawn to mixtures comprising determined dosages of lipids based upon subjects.
3. Arbitrarily selected *only* the narrowest embodiments of oil mixtures for patent grant[27]
4. Several limitations were excised or discounted from the claims in order to limit the allowable subject matter to certain oil mixtures.[28] (See Section IV).
5. Arbitrary §§ 101 and 102 rejections were forced and maintained despite strong rebuttals with arguments and evidence.[29] (See Section IV).

Additional pressure was placed upon the Applicant during interviews in form of the following statements from USPTO, in order to force narrow position:

- The subject claims are inherent in nutrition.
- Patents on omega-6 and omega-3 have to be restricted because many people work with them.

However, inherency can only be alleged if the prior art (nutrition) necessarily functions as claimed, which it does not. Rather the art overwhelmingly teaches the opposite, including in the cited

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[26] Office Action of October 11, 2013, p. 15.
[27] USPA 12/426,034 Interview Summary mailed by USPTO on January 31, 2014, finding only narrow oil mixtures (3) and (4) in then claim 91 to be allowable.
[28] USPA 12/426,034 Office action dated March 10, 2015, p. 4-6.
[29] USPA 12/426,034 Office actions dated September 22, 2015 and PTAB Decision dated April 15, 2016 (Annex G).

references, as demonstrated above in Section III.1 and below in Section IV.1.

Further, restricting patents on omega-6 and omega-3 because many people work with them all but ensures that there will never be any meaningful advancement in this art. Many people work with restricted formulations is precisely why there is so much confusion and so much noise in the art. Everybody enters the marketplace and sells products based on the artificially patent-created boundaries, marketing to masses with conflicting marketing messages. This is how omega-3 got out of hand and hyped out of context in the first place, because many restricted patents on omega-3 have been issued.

The restrictions are in part because of USPTO's revenue maximization drive. Higher number filings, restricted patent grants, and divisional applications, all increase revenue to USPTO. Therefore, USPTO is happy to give composition A to Party-1, composition B to Party-2… and composition ZZZ to Party-nnn. These restrictions especially are applied to nutrition patents. This keeps revenue rolling in to USPTO and inventors given token patents and some revenue stream, but public confused, ill, and on drugs, because nobody truly gets the head or the tail and a system is set that perpetuates confusion.

Most important goal of USPTO is advancement for the betterment of human condition, revenue comes second. If USPTO inhibits advancement for revenue, then USPTO is failing its goal.

This unfavorable treatment of nutrition patents is also evident from the Federal Circuit's review of the appeal in case of the '034 Application. For example, the Federal Circuit Opinion (Annex H) states at middle of page 5,

> The Board found that the "casing" and "dosage" terms do not impart patentability to the claimed compositions, and we agree, for the specification states that these claim elements are not limiting, and does not describe any assertedly novel characteristics of these components or their formulations.

The allegation that the limitations "casing" and "dosage" are "not limiting" is in violation of a large body of the Federal Circuit's own and Supreme Court's precedents and ruthlessly obliterates the Specification. For example, in *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-81 (Fed. Cir. 1995) (en banc) the Federal Circuit stated,

> "Both this court and the Supreme Court have made clear that all elements of a patent claim are material, with no single part of a claim being more important or "essential" than another. See *Fay v. Cordesman*, 109 U.S. 408, 420-21, 3 S.Ct. 36, 243-45, 27 L.Ed. 979 (1883); *Pennwalt Corp. v. Durand-Wayland, Inc.,* 833 F.2d 931, 936 (Fed.Cir.1987) (in banc)."

Further, the Specification never said that "these claim elements are not limiting". The importance of "dosage of omega-6" is the most important feature in the Specification, emphasized throughout, especially in tables 10-14 and 21, Examples 11-27 and original

claim 3. Specification paragraph [00106] specifically states, "It is intended that the following claims define the scope of the disclosure."

Then on what basis did the Federal Circuit decide that "casings providing controlled delivery of the formulation to a subject" and "dosage" recited in the claims is not limiting?

Additionally, the Federal Circuit itself has ruled in a large number of cases (see Section IV.1.iii-ix below) that the prior art must necessarily function as claimed and a competitor must be able to obtain the claimed subject matter from the prior art to be considered anticipatory.

Then on what basis did the Federal Circuit opine contrary to its own holdings?

Furthermore, in *Berkheimer v. HP, Inc.*, 881 F.3d 1360 on February 8, 2018, in case of a software patent (one month before issuing the problematic opinion in case of the '034 Application), the Federal Circuit held,

> "The question of whether a claim element or combination of elements is well understood, routine and conventional to a skilled artisan in the relevant field is a question of fact. Any fact, such as this one, that is pertinent to the invalidity conclusion must be proven by clear and convincing evidence. *See Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011)…Whether a particular technology is well-understood, routine, and conventional goes beyond what was simply known in the prior art. The mere fact that

> something is disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional."

Yet in case of '034 Application, which repeatedly asserts that the subject matter is poorly understood (e.g., see paragraphs [006]-[007], Annex A) and despite <u>eleven</u> testimonies from skilled persons to this effect (see subset in Annexes S-X) and numerous publications (Annexes Y-AB), and the cited art itself teaching the opposite, the Federal Circuit uttered <u>not even a single word</u> about this in its opinion (Annex H). In face of all the evidence, the Federal Circuit rather apathetically stated, "claims are directed to the omega-6 and omega-3 fatty acids that occur in nature" (Annex H, p. 12), disregarding the numeric limitations in the claims.

Further, *exactly one day* after the Federal Circuit affirmed *Berkheimer v. HP, Inc.*, refusing to rehear the case by a near-unanimous *en banc* decision (May 31, 2018), the Federal Circuit refused to reconsider its *<u>exact opposite ruling</u>* in the present case upon the Petition for Rehearing and Rehearing En Banc on June 1, 2018 (Annex I).

These violations of the USPTO and the Federal Circuit have been repeatedly called to the attention of the Supreme Court in several petitions (see Annexes K-Q). The Supreme Court has turned a deaf ear, thus far.

Thus, the entire US patent system disfavors patent grant to nutritional solutions, which the rest of the world follows, creating unfavorable economics

for prevention and grave patent-practice-made humanitarian crises. See discussion below in Section V.

6. Special Interest Groups Including the Patent System Thwart Preventative Efforts

It is self-evident that the treatment industry, the sellers of drugs and devices and the providers of surgical and other procedures, work against preventative efforts such as tailored lipid dosages, but that the patent system run by the Government of the United States would thwart such efforts, as evidenced above and below is most disturbing. Significant patent scope is not only necessary to rise above the noise in the art, but also to fend off the efforts of those who undermine such efforts. Therefore, at least the Government should not compromise the effort by unnecessarily restricting the nutrition patents.

IV. Mutilation of Title 35 USC in Examination and Appeal Review of the '034 Application

1. USPTO Mutilated Title 35 of the United States Code and a Large Body of Case Law to Sustain Rejections

USPTO mutilated the law and wiped out the separation between 35 USC §§ 101, 102, and 103, usurping Congress' power and purpose behind those separations to an extreme that has never been done before.

In *six Office actions* over several years USPTO was unable to sustain § 102 rejections because no prior art taught identical claimed features, and § 103 rejections could not be sustained because of new insights presented, disadvantages predicted in the prior art, unexpected results, and opposite teachings in the prior art and critical unmet public health need. Thereafter, in the *7th Office action* in October 2013 and onwards USPTO mutilated the claims and the law and *forced* §§ 101 and 102 rejections.

As evidenced in Section III.1 above, prior to April 2008 the art overwhelmingly taught the opposite of the claimed inventions: low intake of omega-6 and low omega-6 to omega-3 ratios, and high intake of omega-9 (monounsaturated fatty acids), and failed to understand peculiar dose-effect of omega-6. A prior art teaching the claimed combinations has not surfaced in 10 years of worldwide prosecution of the corresponding applications. This bears out in *all* of the citations by USPTO.

For example:

- Cited arts under § 101: Olive Oil (Annex B) and Walnut Oil (Annex C) are interactive webpages describing nutrient content in a batch of each oil in capacity measures ranging from 1 tsp to 1 cup, and 4g to 100g. That is neither are the references teaching "dosage [amount determined for administration]" of omega-6 and omegae-3, nor are the references teaching "intermixtures of lipids" in "casings" to control lipid content/delivery or provide

daily variety as taught in Specification (Annex A, e.g., paragraph [0030] and Table 3).

– Cited arts under § 102: Olives (Annex D) and Walnuts (Annex E) found on archives of whfoods.com webpages also describe nutrient content, specifically reciting "Nutritional Profile" on each of the main pages of Olives and Walnuts and "In depth nutrient analysis" on the associated pages. Furthermore, under "How to Enjoy" each of the Olives and Walnuts pages teach mixing olives/ walnuts with other foods and the website teaches "ratio of omega-3 to omega-6…around 1:2…decrease the amount of omega-6 fatty acids in your diet, while increasing the amount of omega-3 fatty acids" (Annex AB).

– Cited art under § 102: Mark (Annex F) is inoperable and it teaches little of relevance to current claims because it teaches contradicting omega-6 to omega-3 ratios in col.2.ll.37-38 versus col.4.ll.21-25; it teaches incomplete lipid profile in the table in column 4 (86% of fatty acids in line 60); it gives an inoperable table in column 6 ("whey" is 100% yet other ingredients are present); it does not teach dosage of omega-6; and it does not teach the effect of other lipids on the requirements of omega-6. Skilled persons have testified to Mark's inoperability and their inability to arrive at the claimed inventions from Mark. See Annex T para [004], Annex U para [005] and [0022], Annex V para [0010] and [0013],

Annex W para [009]-[0017], and Annex X para [3.3.10., and 3.4].

In order to support the rejections, USPTO gave no weight to the limitations "formulation", "dosage", and "casings providing controlled delivery of the formulation to a subject, wherein at least one casing comprises an intermixture of lipids from different sources" and alleged that "intermixture of lipids from different sources" is a product-by-process limitation.[30] Similarly, many limitations were written out of the claims, for example, "daily amounts of fatty acids for the subject based on one or more factors selected from…" from Claim 98.

Further, even after *admitting* that the combination of ratios recited in Claim 102, 107, and 119 does not occur in nature, USPTO rejected the claims under § 101 for *combining* fatty acids that occur in nature into the formulation of the claims.[31]

Furthermore, not only did USPTO erroneously treat oils as "products of nature"[32] but they also improperly treated the man-made instructions on the webpages as "product of nature." All 55 claims were ruthlessly rejected as being drawn to "products of nature," and patent ineligible under § 101. (See claims at the end of Annex A and USPTO Decision at Annex G).

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[30] PTAB Decision dated April 15, 2016, pp. 7—9 (Annex G).
[31] Final Office action dated September 22, 2015, p. 36.
[32] Oils are not products of nature; they are made from nuts/seeds and have different properties and nutrient content from nuts/seeds. Extensive arguments and evidence to this effect are on record.

After excising limitations, USPTO alleged that Applicant had not demonstrated marked structural differences or transformation over Olive Oil or Walnut Oil, citing Funk Bros. Seed Co. v. Kalo Inoculant Co., Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948) and *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.* 133 S. Ct. 2107 (2013).[33]

Both the citations of Funk Bros. and Myriad under § 101 were contrary to 35 USC § 101 and Congress' intent!

Funk Bros. was decided under the now obsolete 35 USC § 31 (1946) that governed *both* patent-eligibility and novelty, which described "Inventions Patentable" as:

> "Any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvements thereof…not known or used by others in this country, before his invention or discovery thereof, and not patented or described in any printed publication in this or any foreign country, before his invention or discovery thereof..."

Congress using *its authority* had revamped Title 35 USC via the 1952 Patent Act, setting up *separate* standards for eligibility under § 101 and for novelty under § 102, and introducing *new standards for non-*

[33] PTAB Decision dated April 15, 2016 pp. 9-14 (Annex G).

obviousness under § 103. The 1952 act was enacted precisely because having eligibility and novelty decided together under one section was problematic, and because there was great ambiguity in what it means to "invent." Congress after great deliberations decided that among conditions for patentability *non-obviousness* was the correct statutory standard rather than "invention" because "invention" is meaningless and lacks clarity[34] and accordingly set the standards in § 103.

Congress set the test for patent eligibility under Title 35 USC §101 of the 1952 Patent Act as:

> "*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*."

Noticeably missing from §101 are the word "structural difference" or "transformation" as a precondition to "obtain a patent therefor", as required by USPTO. Also, what standard of "structural difference" or "transformation" is sufficient for patent-eligibility. As with "invention," there is no standard of "structural difference" or "transformation."

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[34] "*Efforts to Establish a Statutory Standard of Invention: Study of the Subcommittee of Patents, Trademarks, and Copyrights of the Committee on the Judiciary*" United States Senate; Eighty-fifth Congress, First Session Pursuant to Senate Resolution 55, Study No. 7 (published 1958)

Thus, USPTO improperly applied *Funk Bros.* where alleged want of "invention" was the issue, which was overruled by Congress via the 1952 Patent Act. Further, USPTO improperly applied *Myriad*, where the claims were drawn to isolated DNA and not expressed in terms of chemical composition. Even then the Supreme Court did find man-made cDNA to be patent-ineligible in *Myriad*.

In contrast, the subject claims are most clearly drawn to man-made *composites* of omega-6, omega-3, and/or other lipids "from different sources," and thus without a doubt the claimed *formulations* clearly fall within the ordinary, contemporary and common meaning of a "composition of matter" under § 101.

Further, the "casing" limitation also falls within the definition of a "manufacture" according to the common meaning of "manufacture" as in § 101.

Still further, the claims represent an important new and useful discovery in nutrition, and the USPTO de facto removed the word "discovers" from § 101.

USPTO usurped Congress' power and rewrote 35 USC § 101 as follows:

> "*Whoever invents ~~or discovers~~ any new and useful ~~process~~ transformation, machine, ~~manufacture, or composition of matter,~~ or any new and useful improvement thereof, may obtain a patent therefor...*"

This re-write of § 101 is an instance of extraordinary usurpation of judicial powers from interpreting statutes to completely redrafting them. It is most disturbing that the USPTO unlawfully abrogated the "discovery," "process," "composition of matter," and "manufacture" language actually found in 35 U.S.C. § 101 from numerous claims at issue in favor of vague concepts "structurally different" or "transformation" or "invention" that the Congress has expressly rejected in deliberations for the 1952 Patent Act.

USPTO also usurped Congress' power and rewrote 35 USC § 102. The rejections under § 102 are contrary to 35 USC § 102 and Congress' intent!

The legal requirements for anticipation rejection under § 102 are very *strict* and rightly so. In order to anticipate the applicable prior art must *disclose and enable the exact same invention* with every single element as recited in the claims. The underlying principle of anticipation rejection is that public—skilled persons including competitors—has been fully informed of the exact solutions and how to practice them and there can be no doubt about this. This is built into Title 35 USC.

> § 102 states,
> "*Novelty; Prior Art.—A person shall be entitled to a patent* ***unless****—*
> *(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention...*" [Emphasis added].

In contrast § 103 states,
"*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.*"
[Emphasis added].

Specificity in patent law has always been held as not anticipated by general prior art disclosure, and *neither the USPTO nor the courts* have had any difficulty in examining and upholding *specific disclosure and enablement* as not anticipated by general prior art. See representative jurisprudence below:

i. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

ii. A reference disclosing "alkaline chlorine or bromine solution" embraces a large number of species and cannot be said to anticipate claims to "alkali metal hypochlorite." *In re Meyer,* 599 F.2d 1026, 202 USPQ 175 (CCPA 1979).

iii. Anticipation law does not permit to fill in missing limitations simply because a skilled

artisan would immediately envision them. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 851 F.3d 1270, 1274 (Fed. Cir. 2017).

iv. "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." In re Oelrich, 666 F.2d 578, 581 (CCPA 1981.

v. The anticipation analysis asks solely whether the prior art reference *discloses and enables* the claimed invention." "Under the principles of inherency, if the prior art *necessarily* functions in accordance with, or includes, the claim limitations, it anticipates." *Perricone v. Medicis Pharm. Corp.* 432 F.3d 1368, 1376 (Fed. Cir. 2005). [Emphasis added].

vi. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art).

vii. In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrow range, and the reference teaches a

broader range, other facts of the case, must be considered when determining whether the narrow range is disclosed with "sufficient specificity" to constitute an anticipation of the claims. Compare *ClearValue Inc. v. Pearl River Polymers Inc.,* 668 F.3d 1340, 101 USPQ2d 1773 (Fed. Cir. 2012) with *Atofina v. Great Lakes Chem. Corp,* 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006).

viii. If little is known in the prior art about the nature of the invention and the art is unpredictable, the disclosure would need more detail as to how to make and use the invention in order to be enabling. *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004) ("the public's end of the bargain struck by the patent system is a full enabling disclosure of the claimed technology.")

ix. "[A]nticipation under § 102 can be found only when the reference discloses exactly what is claimed and that where there are differences between the reference disclosure and the claim, the rejection must be based on § 103 which takes differences into account." *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

Thus, there is clear and ***purposeful*** distinction between lack of novelty and obviousness, in that the law recognizes that in order to destroy novelty a prior art document must disclose and teach how to practice the ***identical*** invention then only it can be said that this is in possession of the public.

Furthermore, a selected range from a broader numerical range is considered novel.

For instance, if there were a reference that exactly described and enabled a formulation to cure common cold permanently, then common cold would be cured. It would defy every conceivable logic if there is a reference that exactly describes and enables the formulation to cure common cold (e.g., dosage of compound A above X g/day), yet billions of humans repeatedly suffer the misery of common cold. Therefore, it is flawless if a reference *exactly* describes and enables claimed limitations, then such claims are not novel.

However, if exact same formulation is *not* described in the prior art, it is *not* clear what aspect of the prior formulation is problematic (e.g., how much compound A in absolute and relative to compound B), and there are *opposite teachings* to the claimed formulation (e.g., dosage of compound A below X g/day) and the public continues to suffer from the misery (like common cold), then the claimed formulation (ratio of compound A to compound B Y:1 and compound A above X g/day) can neither lack novelty nor be obvious.

Thus, § 102 requires *identical* disclosure of the claimed subject matter, which requirement is not met by Olives, Walnuts, or Mark.

USPTO excised the specific differentiating features "dosages", "casings providing controlled delivery" and "intermixtures of lipids from different sources," in order to force rejections under § 102

because claims were non-obvious under § 103 because of new insights presented, disadvantages predicted in the prior art, unexpected results, and opposite teachings in the prior art and critical unmet public health need.

Furthermore, USPTO reconstructed Mark that gives *no* teaching about "dosage of omega-6 fatty acids" *no* teaching of how other lipids affect the activity of omega-6 under § 102. Because Mark recited contradicting omega-6 to omega-3 ratios in col.2.ll.37-38 versus col.4.ll.21-25, and gave inoperable tables in columns 4 and 6, USPTO reconstructed Mark's recitation "the source of omega-6 fatty acids is present in the range of approximately 4-6% of the total calories. The omega-3 fatty acid source preferably present in the range of approximately 0.8-1.2% of calories"[35] into ratio of omega-6 to omega-3, though same source can be source of omega-6 and omega-3 (e.g., canola oil) rendering the recitation meaningless; and USPTO reconstructed concentration (g/1000 ml) into dosage. Mark also does not *necessarily* function as an "intermixture of lipids from different sources," reciting "a lipid source" in claim 1, 9, and 15. (See Annex F). Thus, USPTO cherry-picked Mark recitations and combined as convenient to sustain rejections.

Olives, Walnuts, and Mark rejections, which would have been applied under § 103 were applied under § 102 because § 103 could not be sustained due

[35] PTAB Decision dated April 15, 2016, pp. 19-20 (Annex G).

to opposite teachings in the art—including in Olives, Walnuts, and Mark.

In any case, Mark is not dispositive because subject Claim 91 and dependent claims, and subject Claim 82, which can replace independent Claim 65, are not rejected under Mark.

Thus, this is an *extreme case of improper rejections by USPTO* of an extremely important invention directed to "composition of matter" "dosages" and "controlled delivery" over *individual foods* under §§ 101 and 102 despite opposite teachings in the art as a whole including the cited art. Though tables describing possible content of *some* nutrients in *individual foods* are in public domain, but popular media, international scientists, various governments, and industry overwhelmingly teach to mix these foods to achieve low absolute and relative intake of omega-6 fatty acids[36]? *In other words, the individual foods in the prior art have neither disclosed nor enabled the solutions nor solved the public suffering.*

Neither would an individual food composition enable a skilled person to inevitably practice omega-6 dosages as taught in the subject disclosure based on state of the art at the time of the disclosure, nor would it be immediately apparent to skilled person to practice the dosages as taught and consider omega-6 concentration in relation to total lipids from individual foods, nor is it proper to interpret

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[36] Ip et al. 1985 supra; Lands 1986 supra; Simopoulos et al. 1999 supra (Annex Z); Lands 2005 supra (Annex AA); WHFoods.com (Annex AB); Wikipedia (Annex AC).

equivalents not disclosed in the references, that is a matter of obviousness. Furthermore, as evident from Annex AC, there is still debate in the art on the claimed subject matter. Therefore, at least lack of enablement in the cited art is a dispositive point to ruling non-anticipation.

Holding scope of the inventions against the Applicant USPTO rejected *all* claims under the pretext of §§ 101 and 102 because rejections under § 103 could not be sustained, and USPTO wiped out the separation between §§ 101, 102, and 103 and usurped Congress' power and purpose behind the separations.

2. US Court of Appeals for the Federal Circuit Rubberstamped USPTO Without Meaningful Review as Required by Administrative Procedure Act

The Federal Circuit affirmed the USPTO in March 2016, without giving a meaningful review, and issued an evasive disjointed opinion. See Annex H.

The case demonstrates *astounding breadth* of abuse of discretion by the Federal Circuit *at least on the following eight counts*:

i. Condoned USPTO's mutilation of the claims by excising limitations,
ii. Condoned USPTO's rewriting of §101 to strike, "composition of matter", "manufacture", and "process" from the statute,

iii. Condoned USPTO's requirement of "structurally different" or "transformation" under §101,
iv. Failed to cite eligibility and anticipation law based upon which the case is decided,
v. Failed to meaningfully review §102 rejections,
vi. Acknowledged prosecution disclaimer of single source like olives/walnuts, then disregarded it and affirmed §102 rejection over olives/walnuts anyway,
vii. Failed to review many claims including independent claims 91,
viii. Dismissed *eleven* expert testimonies, without a word in the opinion.

The opinion jumps from one context to another inexplicably; one doesn't know which claim is being reviewed and what law is being applied. For example, at page 10 opinion states,

> "The Applicant also argues that claim 128 is distinguished from natural products, and is not anticipated based on the limitation that the compositions contain "nuts or their oils" obtained from "almonds, peanuts, and/or coconut meat." The Board held that admixture with other natural products of known composition was not shown or stated to change the nature of the compositions, citing *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948)…The Board correctly held that claim 128 does not avoid the rejection on the ground that the claims are directed to known natural products."

However, Claim 128 is dependent on Claim 91, which the Federal Circuit *never reviewed*. How can Federal Circuit opine upon a dependent claim without reviewing the elements of the independent claim first? Further, Funk Bros. citation against Claim 128 is the only citation under § 101 by Federal Circuit, there is no other citation even under §102. So one is left guessing as to what principles of law are being applied?

Further, at page 11 the opinion states,

> Claim 102 recites specific ratios of **polyunsaturated, monounsaturated**, and saturated fatty acids. Claims 107 and 119 present the fatty acid content recited in claims 98 and 91, respectively, in Tables in the specification. The Board observed that the servings of olive oil and walnut oil shown in the references contain **omega-6 and omega-3 fatty acids in amounts within the Applicant's claimed ranges**. Thus the Board held that the "intermixture of lipids from different sources" does not distinguish the claims from natural products because the 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, nor that a different source would necessarily impart characteristics to the formulation which were absent when a single source was used." Board Op. at *8. [Emphasis added].

However, the Federal Circuit comments above pertain to Claim 65 not claims 102, 107, and 119. For example, what do "omega-6 and omega-3 fatty acids in amounts within the Applicant's claimed ranges" have to do with "ratio of monounsaturated fatty acids to polyunsaturated fatty acids?" The Federal Circuit *failed to answer* the argument that claims 102, 107, and 119 expressly recite numeric limitations directed "***ratio of monounsaturated fatty acids to polyunsaturated fatty acids* is in the range of 1:1 to 3:1**"[37], which is *not* met by olive oil or walnut oil.

It is well established that failure to answer an argument is tantamount to conceding that there is no answer. The opinion was intentionally written evasively and in a disjointed manner to evade justice, because the Federal Circuit had no answer. There is not one instance of impropriety but improprieties on all counts. The Federal Circuit's improprieties were also established above in Section III.5.

The whole point of the claimed inventions is that nature does not provide the required nutrients in desired combinations and restrictions and is unpredictable. The allegation that the claimed products occur in nature is an oxymoron. The Federal Circuit's actions demonstrate the system's bias against nutrition.

One does not expect such travesty of justice from the Federal Circuit, the second highest court in the nation. This is extremely demoralizing for the

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[37] Appeal Brief p. 34, 58-59, 77-78.

citizens, above and beyond the public health consequences.

3. Reticence of the Supreme Court of the United States

The Supreme Court has not accepted the Petition for a Writ of Certiorari (Annexes K-M) (case no. 18-277) and the Supreme Court has overlooked the extreme abuse of discretion in examination and appeal review and denied the Petition for a Writ of Mandamus (Annexes N-P) (case no. 18-1274).

In view of intervening circumstances in the form of the US Senate's recently published proposed language to reform Title 35 U.S.C. § 101 based on problematic behavior of the USPTO and the lower courts[38], Petition for Rehearing for the Writ of Certiorari (case no. 18-277) was submitted to the Supreme Court on July 11, 2019 (Annex Q), which is currently pending.

It is disturbing that the Supreme Court considers it more important to protect the constitutional rights of heinous criminals, see *Kennedy v. Louisiana*, 554 U.S. 407 (2008) under the 8th Amendment to not be subjected to "cruel and unusual punishment" than protecting the same rights of general public to not be put under the knife or subjected to drugs and devices unnecessarily, which happens when patent system favors patent grants to drugs over nutrition.

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[38] https://www.tillis.senate.gov/services/files/E8ED2188-DC15-4876-8F51-A03CF4A63E26

Additionally, the Supreme Court disregards constitutional rights of inventors to due process and equal protection of laws under the 14th Amendment. Supreme Court should have afforded the same protection of laws to the Applicant and Inventors, such as to *Dickenson v. Zurko*, 527 U. S. 150 (1999) holding "the importance of not simply rubber-stamping agency fact-finding." Id 162., and to *Myriad* finding cDNA to be patent eligible.

The Supreme Court's declinations are further travesty of justice.

V. Patent Practice-made Humanitarian Crises

The dubious patent practices discussed above have created at least two kinds of humanitarian crises, first towards the public at large, and second towards independent inventors and small entities.

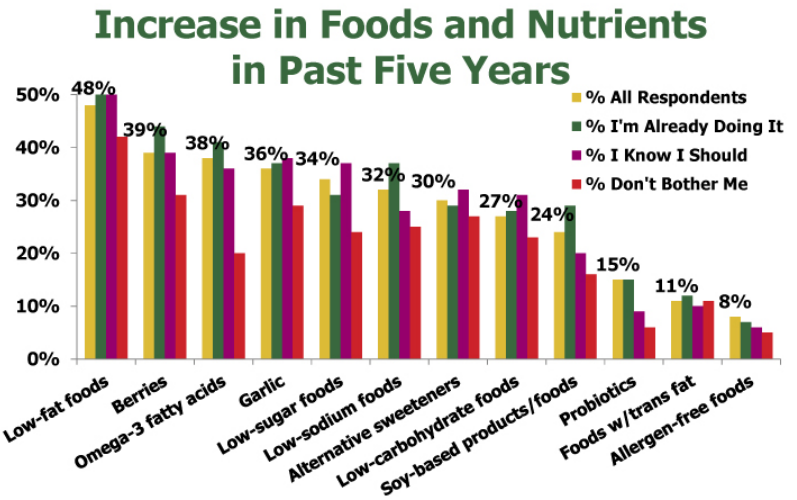
1. Humanitarian Rights Violations of Public at large

Though Title 35 USC does not differentiate patent grant to nutrition versus drugs, but as evidenced above patent practice does. If Applicant's claims were directed to a drug candidate similarly differentiated over the prior art, the patent would have been granted many years ago.

When patents are favourably granted to drugs and devices it makes them more financially rewarding, enabled by the large profit margins from prompt and strong monopoly. Then, investors, marketers, and providers heavily fund and tout

drugs and devices and make public dependent on drugs and devices.

When nutrition patents are granted, they are severely restricted which causes confusion and makes the problem worse, as USPTO has done in the subject case under the pretext of §§ 101 and 102. Piecemeal patents do not solve problems and cannot advance nutritional arts. Rather, they create more confusion and excesses/ imbalances of certain foods and nutrients in the nutrition supply and individual consumption, as evidenced by Nutrition and You: Trends 2008; Survey by American Dietetic Association.[39]



For example, Applicant pointed out in examination of USPA 13/877,847 that Examiner is improperly restricting the claims to small amount in the package, rather than dosage customarily

[39] http://www.eatrightpro.org/~/media/eatrightpro%20files/media/trends%20and%20reviews/nutrition%20and%20you/trends_2008_presentation.ashx; slide 37.

indicated on product packaging, allowing multi-dose packaging, and that the restrictions will force the pricing of the claimed consumer product out of the market and multiply packaging and create waste and burden the environment and humanity. Examiner responded that it was not her problem and forced the restriction under the pretext of clarity.[40]

Thus, thousands of patents are granted on very restricted formulations and methods leading to advertising campaigns that cancel each other out and cause mass misinformation. This leads to total confusion and public stops believing everything.

Therefore, the patent system is obstructing advancement in nutrition.

The misdirected patent policy is why public has been paying for lipid patents since 1870s[41] but the problem has not gone away. The very issue is that patent protection is not provided to formulated lipid dosages for subjects, which is the necessary foundation, but patent protection is provided to a restricted amount in a package, or different oil mixtures, or structurally altered molecules, or designing new oil varieties, which is of limited value because lipid content will still depend on where and how a species is cultivated.

Such missteps take us farther and farther from genuine solutions, in the meantime more harm is caused to public health. For example, it was a

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[40] USPA 13/877,847 Office action dated August 13, 2018, p. 20-21.

[41] https://en.wikipedia.org/wiki/Margarine

German patent of structurally altered fats[42] that gave us hydrogenated fats and caused worldwide diseases for 100 years[43], which activity is still ongoing[44] despite damage caused previously.

Thus, occasionally, some oils, mixtures, molecules are promoted but then they realize it does not solve the problem or causes more problems and come back to square one. The result is lipid delivery to public has not substantially advanced in 6000 years, since invention of oils. Though oil manufacturing has advanced, but to date random oils are randomly added to foods.

Thus, the patent practice is skewing the marketplace in favor of drugs and devices and taking public farther from prevention, while the public continues to suffer. As noted above 117 million Americans from suffer from chronic diseases and 80% of women suffer from hormonal issues, which can be abated by tailored lipids.

This is a humanitarian crisis from which public has been suffering for at least 100 years, since industrialization of nutrition started to prevail. If patents were equitably granted to nutrition and drugs, then at least nutrition and prevention have a fair chance. However, in the current scenario, where the patent system has compromised and sabotaged efforts such as ours with undue restrictions and 10

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[42] https://en.wikipedia.org/wiki/Wilhelm_Normann
[43] https://en.wikipedia.org/wiki/Crisco
[44] E.g., U.S. Patent 9,351,502 "Oxidized and partially hydrogenated oil or fat" issued May 31, 2016

years of delay in patent grant, nutrition has little chance and the crisis may get more severe.

Net effect is that the patent system is not only obstructing advancement in nutrition, but it is promoting stagnation in nutrition. By obstructing advancement in nutrition, the system is obstructing advancement in medicine also, because we as a society are so consumed in treating what can be prevented that we are not making true downstream advancements in medicine that address issues beyond what can be prevented.

2. Humanitarian Violations of Independent Inventors and Small Entities and Worldwide Consequences of Actions of the USPTO and the Federal Circuit

The patent system neutered our innovation with obstruction and delays because of its bias against nutrition and because they are programmed to restrict. Although, USPA 13/332,251 was granted in May 2019 (US Patent 10292958), it is 10 years after the parent application was filed and after numerous Office actions and appeals and enormous prosecution costs and business setbacks to the Applicant.

It is extremely arduous for small entities and independent inventors to sustain such long prosecution (10 years in the present case). We have had lawyers prosecuting for us off and on, but as a small company we cannot keep that up for 10 years. As a result, we had to self-prosecute before the Appeal Board at USPTO and the Federal Circuit, which apparently was held against us as evident

from the impropriety of the decisions discussed above. In other words, first they compromise small companies with improper objections and delays, and then when small companies are forced to self-prosecute, they hold self-prosecution against the applicants.

This case also illustrates that *pro se* inventors cannot get fair treatment at USPTO or the Courts. As evidenced above in Section III.5, the Federal Circuit gave a favorable treatment to Berkheimer and exactly opposite to us even though the issue of poorly understood factors is stronger in our case than the Berkheimer case. Further, why is the Berkheimer case getting Supreme Court's attention[45] and not ours, though our case has 1000 times more national significance? Only because HP Inc., a big business, filed the petition.

Furthermore, in this case there is evidence of EPO (European Patent Office) copying USPTO's improprieties[46], and many other jurisdictions in turn have copied EPO's and USPTO's improper actions. <u>That is *the Governments are violating independent inventors/small entities (and the public) in collusion*</u>

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[45] https://www.supremecourt.gov/search.aspx?filename=/docket/docketfiles/html/public/18-415.html

[46] Alleged anticipation by individual oils was brought up for the first time by EPO at the Oral Proceedings held on 11 February 2015, following USPTO's allegation of anticipation by individual oils as alleged "products of nature" in the Office action of 18 August 2014 p. 14-20, in case of corresponding US patent application number 12/426,034. Additionally, EPO had raised some far-fetched objections copying the USPTO Examiner, such as referring to "different sources" as "different producer" or "different supplier." See Annex AD.

with each other. Because of this collusion Applicant has had to file scores of extra responses to repeated improper objections and over dozen appeals and lawsuits in various jurisdictions.

Thankfully, some governing bodies in some other jurisdictions have demonstrated greater sense of responsibility, duty, and justice than the United States of America and EPO[47] thus far. For example, Intellectual Property High Court of Japan (in case of Japanese Patent application 2014-099072) and Intellectual Property Trial and Appeal Board of South Korea (in case of Korean Patent Application 10-2010-7026029) have reversed the decisions of their respective patent offices. South Korea has issued a Notice of Allowance, which patent covers claims similar to *both* the '034 Application and the recently granted US Patent 10292958.

However, imagine the burden all these actions have placed on the small company and its proprietors, and how this has obstructed innovation and reduced the time window to implement the critical innovation.

The prosecution delays impede implementation of innovation because investors and strategic partners do not come forward until patent scope is clear. By the time the patent is granted so little patent term is left that the necessary window to nurture the innovation in protected environment is gone.

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[47] The injustice at EPO has been called to the attention of the Administrative Council of EPO. See Annex AD.

It should be noted that disclosure or teaching is not always enough to solve a problem. In cases such the present one, the complex innovation will not take hold in the absence of a sufficient scope and protected term. Just like a tree sapling needs a fence around it to protect from cattle to allow growth, similarly such inventions need the twenty-year patent term for proper implementation. Therefore, the view that the patent system's objective is to induce disclosure, would be misplaced.

Such US practices (in collusion with other jurisdictions) have put human rights and sustainable development in jeopardy.

VI. Conclusion and Remedy Requested

Since USPTO rejection in 2015 in the '034 application, over four years have been lost in appeals at the expense of innovation and public health. USPTO and the Courts successfully obstructed the innovation and public well-being and failed to render justice.

They defeated the very purpose of patents, innovation for betterment of the human condition, the very reason for USPTO's and the patent system's existence!

The Federal Circuit should have shown grave concern upon such violations happening at USPTO that are abusive to inventors, applicants, and are sabotaging implementation of innovation for public

benefit. Under the circumstances the Federal Circuit should have reversed the USPTO.

These actions are extremely detrimental to innovation, public benefit, and the USPTO's charter.

We request the Congress to take action to stop this malfeasance and request the following remedies:

1. Abrogate the USPTO's and the Federal Circuit's Decisions in case of the '034 Application.
2. Due to the extraordinary case of malfeasance on part of the USPTO and the Federal Circuit, adjust the patent term such that the 20 years patent term is counted from the date of allowance of the '034 Application. In the worst case, no more than three years may be deducted from the 20-year patent term for prosecution as per 35 U.S.C. § 154.
3. Reconsider revenue and reward at USPTO, removing incentives for unnecessary restrictions that compromise innovation, and place burden on humanity.

Unless the Congress fully supports this endeavor the current stagnation in the lipid nutrition and the associated public suffering will likely continue for 1000s of years to come.

Respectfully,

/s/ Urvashi Bhagat

Urvashi Bhagat
Chief Executive Officer

ANNEXES A—AD

(Omitted)

(The entire Letter to Congress with Annexes is Available at https://asha-nutrition.com/wp-content/uploads/2019/09/190811LetterToCongress_w_Annexes-compressed.pdf)