IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Jeff Addy	
U.S. Patent No.:	11,248,245	Attorney Docket No.: 47604-0020IP1
Issue Date:	February 15, 2022	
Appl. Serial No.:	14/578,075	
Filing Date:	December 19, 2014	
Title:	PROCESS AND SYSTEMS FOR CATALYTIC MANUFACTURE OF WAX ESTER DERIVATIVES	

DECLARATION OF THOMAS SCHULTZ

I currently hold the opinions set expressed in this declaration. But my analysis may continue, and I may acquire additional information and/or attain supplemental insights that may result in added observations.

I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of the Title 18 of the United States Code.

Dated: June 27, 2023 By: Thomas Schultz, Ph.D.

Thomas Schultz, Ph.D.

CARGILL 2001
Vantage v. Cargill
IPR2023-00589

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I, THOMAS SCHULTZ, PH.D., hereby declare the following:

I. QUALIFICATIONS AND BACKGROUND INFORMATION

1. My education and experience are described more fully in the attached curriculum vitae (APPENDIX A). For ease of reference, I have highlighted certain information below.

2. I received my B.A. Russian Languages/Chemistry-Physics Minor in 1977, my M. Sc. (Chemistry) in 1979, and my Ph.D. in Physical-Organic Chemistry in 1985 all from New York University. My Ph.D. research was funded under an NIH Cancer Research Grant (1977-1981) to myself and Professor G. Underwood of New York University and which included a term at the Naylor Institute For Cancer Research in Westchester, New York. I attended INSEAD, Fontainebleau, France in 1996 for Business Management.

3. I currently consult in the fields of chemistry and chemical materials used in the personal care and over-the-counter products with a focus on product development including intellectual property, formulations, and product safety.

4. My scientific expertise crosses product formulation, new materials development, and hair and skin science. I have extensive experience in the practice and product development, U.S. and international product safety criteria, including human safety testing, product scale-up from bench top to commercialization,

consumer product research, and product packaging stability testing and the international regulations for package labeling. I began work at Clairol, Inc. (Stamford, CT) as a bench chemist being trained in the processes required to develop formulations for hair care including hair coloring, bleaching, shampooing and conditioning and styling, all practices that use oils and waxes in their product compositions. These practices included the evaluation of those chemicals used in personal care products for their efficacious qualities in their ability to form creams and oil-water emulsions. Optimization of the choice such oils and waxes involved iterative formula development based on both laboratory bench testing and the inputs of professional cosmetologists' evaluations to modify the formulations per the sensorial information they provided. The needed steps for performing the initial product stability assessments protocols in order to preview any potential failures of the formulation early in the development process. For example, hair coloring products require an essentially air-free formulation to protect the latent hair dye materials. Product safety protocols were also part of this process including at that time, animal safety studies (e.g. the Draize test on rabbit eyes to predict skin irritation, later replaced with non-animal models such Sintext, etc.) and human safety testing (e.g. the Human Repeat Insult Patch Test, HRIPT) on volunteers and a test for resistance of any microbial growth. These practices are those that have been developed over decades of personal care products testing, and rigorously followed

for products such as hair dyes and bleaches which have the most potential to cause irritation on human skin and scalp so that certain materials are often used based on their safe history.

5. During my career at Clairol, I was promoted through to a Group Manager, supervising a team of from five to ten chemists and laboratory technicians, in hair color and hair care product development, basic hair science research, and novel materials' development (hair dyes, hair conditioning materials, and hair bleaching compositions). During this time I established contract research programs on hair science with The Textile Research Institute (Princeton, NJ) on hair structure and the effects of chemicals thereupon, and skin science including melanogenesis at Yale University (with Dr. J. Pawlek) and The University Of Naples (Prof. G. Prota) and the Medical University of Silesia, Poland (Prof. T. Sarna). This experience of forward searching research on hair enabled new materials development as a model for building a cadre of performance enhancing materials on call for marketing needs. Clairol, as a fast moving consumer goods company with much competition in their respective markets, necessitated performing new product development based on searching for or developing technologies that would solve for unmet performance needs as defined by the consumer. This involved the exploration of various materials or compositions of matter concurrently and systematically setting up many simultaneous formulations and performing the on bench testing and moving the best

performing items into the testing salon. Through this work I became very familiar with many chemical suppliers gaining knowledge of the classes of chemicals, e.g. surfactants, waxes, oils and others.

6. I have several patents from my time at Clairol and made numerous presentations at cosmetic chemists and science meetings. My experience at Shiseido Ltd's ZOTOS division, begin as a Group Manager rising to Vice President of Research and Development and for one year concurrently as Vice President of Manufacturing. I was responsible for all aspects of product development, including formulation development, basic hair science research, formula globalization (the modification of formulations for use at any of Shiseido's global markets), and intellectual property oversight for formulations. Formula globalization required the in-depth knowledge of the materials used in the products such that an intimacy with many chemical suppliers to the trade was established. In this activity, the coordination of materials and parts for product manufacture on the 100,000 pcs and higher scale is not trivial. Materials, especially what are known as the commodity chemicals such as waxes, oils, emulsifiers and similar, were needed in large supply so that those chemicals selected for use in the products were often proprietary, covered by a patent or otherwise unique.

7. My experience at L'Oreal's USA company, COSMAIR, included product research and development for hair color, hair bleaching, hair care and hair styling

for its professional hair care products in the US initially, and then subsequently branching to global brands. My responsibilities included formulation development, product safety, microbial challenge, stability testing, claims development including testing and documentation, patent review and inventions development, competitive products analysis and evaluations, test salon supervision, harmonization of the various brands' formulations to meet L'Oreal's global materials use compliance, external materials and hair science programs and oversight of the scale-up laboratory for the New Jersey facility. I also served as hair color product development liaison between the US R&D and France Clichy Hair Color R&D teams. During this time, I was also responsible for innovations including those for skin care and makeup. Additionally I served as one of the liaisons to the corporate headquarters in France as for intellectually property development.

8. My experience at P&G as Director Skin Care included the development of new skin care technology and the development of 'on-demand' skin care products manufacturing for P&G's reflect.com internet business. This included all aspects of skin care product development (formulations, safety and quality assurance/ quality control parameters, claims development and proofs, usage directions) and small-scale manufacturing at their KOLMAR-Port Jervis, NY facility. My work experience at E. I. DuPont de Nemours (Wilmington, DE), President, Aspect, LLC Division, was as materials and innovations lead market developer. In this role, we

successfully identified and placed both technologies and materials on hand at DuPont to specific unmet performance needs in the personal care product space. My experience at NuSkin Inc. (Provo, UT) was initially as a consultant then as an interim executive for all of their product development, manufacturing (all products provided as finished by 3rd party suppliers), quality assurance and quality control, regulatory compliance, and supply chain needs globally. NuSkin distributes products into more than 50 countries.

9. My experience at Playtex Products, Inc. as Senior Vice President, Chief Technology Officer included all product development (sun-care, infant care, feminine care and personal care products) and their needed claims development and product testing and documentation, regulatory affairs, intellectual property development, safety and Quality Assurance and Quality Control, product scale up, and Consumer Affairs-Complaints.

10. My experience with Baker Street Laboratories LLC was as a consultant to F500 and smaller companies was in the areas of market opportunities, materials development and placement, strategy, claims development, M&A, and legal reviews, litigation support.

11. My experience at Horizon Partners Ventures LLC was as co-founder; a business helps monetizing early stage inventions and innovations through out-licensing or technology sale.

12. I have provided expert consultation for numerous companies since 2002 on product development for hair and skin care products for retail and doctor distribution pathways, new materials development for specialty chemical companies, several 'private label' personal care product companies. My experience with the chemicals and materials used in formulations of personal care and medicinal products including my work as a consultant with materials selection and formulation development that I have provided is listed below:

- **2002: E. I. DuPont**, Technology repurposing; IP re-utilization.
- **2003**: **NuSkin Ltd.** Dermatology based skin care; Sun Protection skin care, makeup globally; Nutritional Supplements. Litigation Support.
- **2009: International Flavors and Fragrances (IFF), Inc.**- General advisement; strategic planning for new initiatives (food & beverage technologies)
- **2009: CRODA PLC.,** Patent Infringement; raw materials strategy.
- **2009-2010: Shaklee Products**. Skin Care/ Sun care; Materials, Formulations and regulatory compliance; Consumer Safety project management: Litigation support.
- **2010-2011: Symrise GmbH**. Skin Care ingredients (organic) and new materials.

- **2011-2012: CRODA, PLC**- Patent Infringement; raw materials strategy.
- **2014-2016: Dermatologist Skin Care Brands- Various luxury brands;** New Product Planning and Procurement- Skin Care/ Sun care; Materials, Formulations and regulatory compliance; Consumer Safety project management.
- **2017- 2019: Presperse Inc.;** Skin Care/ Sun care; Materials, Formulations and regulatory compliance;

13. I have made in excess of forty presentations to industry and academic and professional organizations during my career. In addition, I have approximately sixty US and International patents and patent applications filed predominantly during work with the corporations where I was employed. These are provided in the Addendum along with my publications list. Being an employee of corporations limited publishing in open journals due to trade secret concerns.

14. I have been the recipient of several awards beginning with a National Institutes Of Health Grant Award (1978-80); and within the industries I was employed including The Society Of Cosmetic Chemists Annual Science Award; P&G Research Fellow Award; The Greater Philadelphia Executive Group Annual Award; and have served on the following Boards of Directors position;

- **American Chemical Society** – Retired General Member

- **Product Development & Manufacturers Association** - Past General Member
- **Society Of Gynecological Research** – Past Executive Board Member, expired
- **Executive Research Council** – Technology Executive Committee, consulting member
- **Personal Care Products Council** – Scientific Advisory Council-consulting member
- Past Board of Directors – *The DaVinci Schools*; Los Angeles County Charter School Initiative; retired
- Past Board of Advisors – QED Program, *The City University Science Center,* Philadelphia, PA; as needed

15. I have been retained on behalf of Cargill, Incorporated ("Cargill") to offer technical opinions related to U.S. Patent No. 11,248,245 ("the '245 patent") (Ex. 1001) and prior art references relating to its subject matter. I have reviewed the '245 Patent. In addition to any materials cited in the present declaration, I have also reviewed the following references:

16. Ex. 1004: Melanie Cummings et al., *A natural alternative*, SOAP, PERFUMERY AND COSMETICS (SPC) ASIA (May 1, 1999) ("Cummings");

17. Ex. 1005: James Brown & Robert Kleinman, Trans *Isomers in Cosmetics*, SOAP & COSMETICS at 33 (May 2001) ("*Trans* Isomers 1");

18. Ex. 1006: James Brown & Robert Kleinman, Trans *Isomers in Cosmetics Part 2*, SOAP & COSMETICS at 44 (June 2001) ("*Trans* Isomers 2");

19. Ex. 1007: U.S. Patent No. RE38,141E1 to Brown et al. ("Brown");

20. Ex. 1008: Xuebing Xu, *Engineering of enzymatic reactions and reactors for lipid modification and synthesis*, 105 EUR. J. LIPID SCI TECH. 289 (2003) ("Xu");

21. Ex. 1009: David J. Sessa, *Derivation of a Cocoa Butter Equivalent from Jojoba Transesterified Ester via a Differential Scanning Calorimetry Index*, 72 J. SCI. FOOD AGRI. 295 (1996) ("Sessa").

22. I have also reviewed various supporting references and other documentation (including Ex. 2002: G. Knothe, *Structure indices in FA chemistry. How relevant is the iodine value?* JAOCS, 79 (9) 847-854 (2002)) as further noted in my opinions below.

23. Counsel has informed me that I should consider these materials through the lens of one of ordinary skill in the art related to the '245 Patent at the time of the earliest possible priority date of the '245 Patent, and I have done so during my review of these materials. The '245 Patent was filed December 19, 2014 ("the Critical Date"). Counsel has informed me that the Critical Date represents the earliest

possible priority date to which the challenged claims of ’245 Patent are entitled, and I have therefore used that Critical Date in my analysis below.

24. I have no financial interest in the parties or in the outcome of this proceeding. I am being compensated for my work as an expert on an hourly basis. My compensation is not dependent on the outcome of these proceedings or the content of my opinions.

25. In writing this declaration, I have considered the following: my own knowledge and experience, including my work experience in the fields of chemistry, product development, personal care product manufacturing and materials procurement, chemical materials, quality assurance, mechanical engineering, and biomedical engineering; my experience in utilizing these skills in both industry and teaching those subjects; and my experience in working with others involved in those fields. In addition, I have analyzed various publications and materials, in addition to other materials I cite in my declaration.

26. My opinions, as explained below, are based on my education, experience, and expertise in the fields relating to the ’245 Patent. Unless otherwise stated, my testimony below refers to the knowledge of one of ordinary skill in the art as of the Critical Date, or before. Any figures that appear within this document have been prepared with the assistance of Counsel and reflect my understanding of the ’245 Patent and the prior art discussed below.

II. OVERVIEW OF CONCLUSIONS FORMED

27. This declaration explains the conclusions that I have formed based on my analysis. To summarize those conclusions, based on my knowledge and experience and my review of the prior art publications listed above, I believe that:

- The prior art references relied on in Grounds 1-4 do not teach or suggest "providing a feedstock comprising jojoba wax esters and hydrogenated jojoba wax esters, wherein the amount of hydrogenated jojoba wax esters is 20 % to 50 % by weight of the feedstock;" and
- The prior art references relied on in Grounds 1-4 do not teach or suggest "wherein an oxidative stability index (OSI) of the transesterified product is greater than an OSI of the feedstock."

III. LEVEL OF ORDINARY SKILL IN THE ART

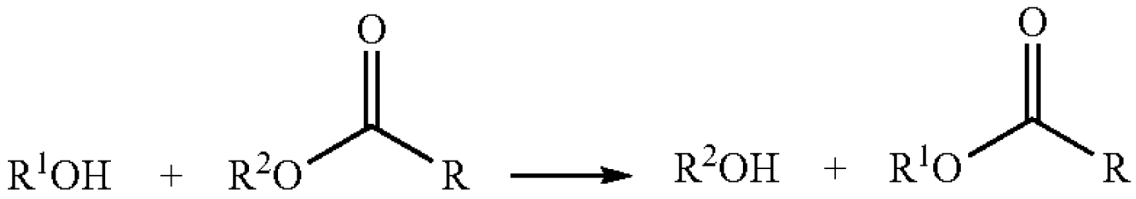
28. In my opinion, a person of ordinary skill in the art as of the Critical Date of the '245 Patent (hereinafter a "POSITA") would have had at least a B.S. in Chemical Engineering, Chemistry, or a related field, and three years of work experience working in the specialty chemicals industry, including in the beauty, personal care, home care, food, or environmental chemical industries or in other specialty chemical industry areas. More education or skill might make up for less experience, and vice-versa.

29. Based on my experiences, I have a good understanding of the capabilities of one of ordinary skill. Indeed, I have worked in these industries, including in personal care or home care industries, have participated in professional organizations associated with these industries, and worked closely with many such persons over the course of my career. Based on my knowledge, skill, and experience, I have an understanding of the capabilities of one of ordinary skill. For example, from my industry experience, I am familiar with what a chemist or product development scientist would have known and found predictable in the art. From my industry experience, I also have an understanding of the knowledge that a person with this academic experience possesses. Furthermore, I possess those capabilities myself.

IV. THE ’245 PATENT

A. Overview of Patent

30. The ’245 Patent describes methods for transesterifying jojoba wax esters using a lipase. Ex. 1001, 1:22-28. According to the specification of the ’245 Patent, “[t]ransesterification involves the process of exchanging acyl groups located on each side of an ester group with an acyl group contained in an alcohol group. *Id.*, 3:28-30. The transesterification reaction illustrated in the ’245 Patent is reproduced below:



Ex. 1001, 3:31-37.

31. Transesterification "permits altering of various physical properties of the transesterified product when compared to the original feedstock," including properties like viscosity, dropping point, oxidative stability index (OSI), carbon chain distribution, and others. *Id.*, 3:38-46.

32. The '245 Patent describes that, at the time of filing of the patent, it was conventional to transesterify wax esters using acidic bentonite-type clay or chemical catalysts. *Id.*, 3:52-56 (acidic bentonite-type clay), 3:66-7:4 (chemical catalysts). The '245 Patent states that with use of chemical catalysts for transesterification processes, "side reactions between the catalyst and components of the feedstock and/or reactants occur during transesterification process" producing "byproducts that reduce the yield of the process and alter the properties of the transesterified product." *Id.*, 4:1-6.

33. The '245 Patent describes that chemically catalyzed transesterification of jojoba oils by chemically catalyzed processes results in side reactions forming various fatty acid methyl esters, but may remove or degrade "steryl esters, sterols,

tocopherols, hydrocarbons, and volatile ingredients in the jojoba oil" resulting in "reduc[tion of] the OSI of the transesterified product to below the OSI of the original jojoba oil." *Id.*, 7:34-42; *see also id.*, 8:29-33 ("the degradation/removal of tocopherols in the chemically catalyzed process adversely affects the oxidative stability (measured by the OSI) and accordingly, the shelf life, of the transesterified product.").

34. The '245 Patent describes that enzymes including lipases can be used in transesterification of wax esters. *Id.,* 4:57-65. In the process of transesterifying a wax ester feedstock using enzymatic catalysis (illustrated in Fig. 2, reproduced below), a "wax ester feedstock passes through one or more catalytic reactors that allow a continuous catalytic transesterification reaction to take place." *Id.,* 5:1-3. The use of enzymatic catalysis in transesterification of wax esters leads to "little or no side reactions between the enzyme catalysts and the reactants." *Id.*, 5:12-13.

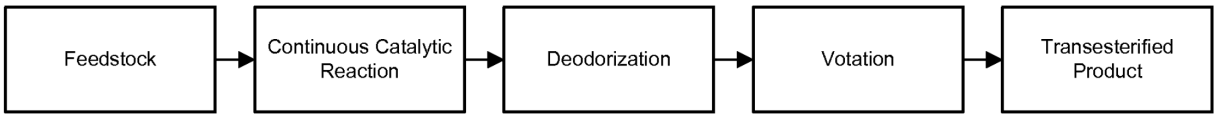


FIG. 2

Ex. 1001, Fig. 2.

35. The '245 Patent describes examples of processing feedstocks including jojoba wax esters with lipases. *Id.*, 6:43-56. The '245 Patent describes that in experiments,

"[s]urprisingly… the OSI of the enzymatically catalyzed transesterified product is greater than that of the feedstock." *Id.*, 9:56-58.

B. Patent Claims

36. The '245 Patent includes one independent claim and four dependent claims. The independent claim describes a process for transesterifying wax esters:

> 1. A process for transesterifying wax ester, the process comprising:
>
> **[1a]** providing a feedstock comprising jojoba wax esters and hydrogenated jojoba wax esters, wherein the amount of hydrogenated jojoba wax esters is 20 % to 50 % by weight of the feedstock;
>
> **[1b]** contacting the feedstock with a lipase; and transesterifying the jojoba wax esters and the hydrogenated jojoba wax esters in the feedstock with the lipase to form a transesterified product;
>
> **[1c]** wherein an oxidative stability index (OSI) of the transesterified product is greater than an OSI of the feedstock.

37. I use the above indicators [1a]-[1c] (as shown above) to identify the limitations of the independent claim throughout this Declaration.

38. The dependent claims 2-5 specify additional aspects of the claimed process of the independent claim:

> 2. The process of claim 1, wherein the feedstock consists essentially of the jojoba wax esters and the hydrogenated jojoba wax esters.
>
> 3. The process of claim 1, wherein the feedstock does not comprise any free fatty alcohols.
>
> 4. The process of claim 1, wherein the transesterified product does not comprise any methyl esters.

5. The process of claim 1, wherein the feedstock does not comprise any methyl esters.

V. PRIOR ART ANALYSIS

39. My findings, as explained below, are based on my study, experience, and background in the fields discussed below. I have also relied on my review and analysis of the prior art, information provided to me in connection with this case, and information I have independently reviewed.

A. The Proposed Grounds Fail to Provide "an Oxidative Stability Index (OSI) of [a] Transesterified Product [that] is Greater Than an OSI of the Feedstock"

40. Claim 1 describes a process for transesterifying wax esters. Ex. 1001, 19:9. The claimed process requires a feedstock "comprising jojoba wax esters ***and*** hydrogenated jojoba wax esters." (Emphasis added). Accordingly, the feedstock must include at least two components: (a) jojoba wax esters and (b) hydrogenated jojoba wax esters. In the claimed process, a lipase is used to form a transesterified product by contacting the feedstock with the lipase. The result of the claimed process is a transesterified product, where the "oxidative stability index (OSI) of the transesterified product is greater than an OSI of the feedstock."

41. The prior art references relied on in each of Grounds 1-4 fail to teach that the OSI of the transesterified product is greater than the claimed *feedstock* because the prior art references make no comparison between an OSI of a feedstock and an OSI

of the transesterified product of that feedstock that comprises both jojoba wax esters and hydrogenated jojoba wax esters.

1. *Ground 1*

42. As discussed in sections below, with regard to Ground 1, Cummings does not teach or suggest the claimed relationship between OSI values of the claimed "feedstock" and its transesterified product formed by use of a lipase. Further, Cummings does not teach or suggest an OSI value representative of a feedstock containing both (a) jojoba wax esters and (b) hydrogenated jojoba wax esters.

a) Cummings does not provide an OSI value of the "feedstock" and an increase in OSI from the feedstock to the transesterified product

43. The Petition fails to show that Cummings teaches or suggests a feedstock that includes the two components of jojoba wax esters and hydrogenated jojoba wax esters as claimed, and that Cummings teaches or suggests a transesterified product with an OSI that is greater than the OSI of the feedstock. With regard to element [1c], the Petition points to Cummings' statement that "[j]ojoba esters demonstrate remarkable stability with OSI values of all jojoba esters greater than 100 hours and as high as 675 hours … the OSI of refined jojoba is around 35 hours." Ex. 1004, 2; *see also* Pet., 38 (Ground 1). Cummings' statement (reproduced below) provides a general comparison of OSI values for "jojoba esters" compared to values for refined jojoba oil. However, the Petition does not show that the refined jojoba oil described

in Cummings is equivalent to the claimed feedstock containing "jojoba wax esters and hydrogenated jojoba wax esters." In fact, Cummings' refined jojoba oil is not the claimed feedstock because nothing in Cummings discloses that the "refined jojoba oil" includes both "jojoba wax esters and hydrogenated jojoba wax esters" as required by claim 1. *See* Ex. 1001, 19:11-12 ("a feedstock comprising jojoba wax esters and hydrogenated wax esters…").

> Oxidative stability of many cosmetic ingredients can be measured to determine an Oxidative Stability Index (OSI).[10] Jojoba esters demonstrate remarkable stability with OSI values of all jojoba esters greater than 100 hours and as high as 675 hours. The OSI of refined jojoba oil is around 35 hours.

Ex. 1004, 2.

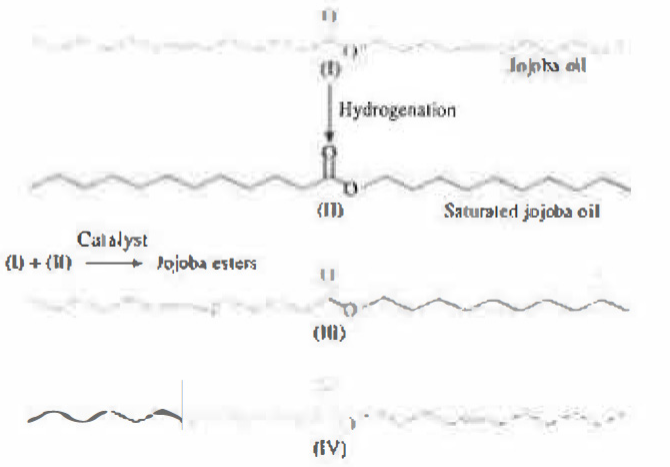
44. The Petition does not include any evidence that Cummings discloses the claimed relationship of "an oxidative stability index (OSI) of [a] transesterified product [that] is greater than an OSI of the feedstock," where the "feedstock compris[es] jojoba wax esters and hydrogenated jojoba wax esters." (Element [1c]). The Petition provides no proof that Cummings provides an OSI value of the feedstock, which must include both jojoba wax esters and hydrogenated wax esters as claimed.

45. Instead, the Petition relies on Cummings' description of *refined jojoba oil* and its associated OSI value as the feedstock and feedstock OSI value. *See* Pet., 38,

68. However, the OSI value of the refined jojoba oil described in Cummings is not relevant to the claimed feedstock or claimed relationship between feedstock and transesterified product in element [1c]. Neither Cummings nor the Petition explains or describes refined jojoba oil as a feedstock that includes both "jojoba wax esters and hydrogenated jojoba wax esters." Accordingly, the Petition does not demonstrate that Cummings' refined jojoba oil is representative of a feedstock as recited in claim 1.

46. Additionally, a POSITA would have understood that refined jojoba oil does not contain hydrogenated jojoba wax esters. For example, Cummings illustrates that jojoba oil must undergo a process of hydrogenation in order to produce a saturated jojoba oil. *See* Ex. 1004, Fig. 1.

Figure 1 - Jojoba ester production



Ex. 1004, Fig. 1.

47. Cummings does not describe the refined jojoba oil as including hydrogenated jojoba wax esters – instead Cummings illustrates that the oil must be processed to achieve hydrogenation. *See* Ex. 1004, Fig. 1. The Petition also does not provide any analysis that would indicate that Cummings' refined jojoba oil would have contained hydrogenated jojoba wax esters. *See id*.

48. The Petition's reliance on Cummings' refined jojoba oil fails to account for potential OSI contributions resulting from the presence of hydrogenated jojoba wax esters in the claimed feedstock. Even if the "refined jojoba oil" OSI given in Cummings were representative of the jojoba wax esters of the claimed feedstock (which is not conceded), the Petition does not identify the second feedstock component in Cummings, and the OSI associated with Cummings' refined jojoba oil is not representative of an OSI of the claimed feedstock containing both components.

49. The Petition fails to explain that the refined jojoba oil pointed to as the alleged feedstock includes only one of the two required components of the claimed feedstock,[1] and also fails to account for the contributions of both components of the

[1] The Petition does appear to acknowledge that the refined jojoba oil cannot be equivalent to the claimed feedstock containing two claimed components, because the Petition states that "the refined jojoba oil that forms ***part of*** the

feedstock to the OSI. Cummings describes OSI values for jojoba esters and refined jojoba oil, but does not describe an OSI value for a feedstock containing both jojoba wax esters and hydrogenated jojoba wax esters. Because Cummings does not provide an OSI value corresponding to the claimed feedstock, Cummings does not teach or suggest the "oxidative stability index (OSI) of the transesterified product is greater than an OSI of the feedstock," as recited in claim element [1c].

b) Cummings' jojoba wax esters are not the claimed "transesterified product"

50. The Petition fails to demonstrate that Cummings' jojoba wax esters are analogous to the claimed "transesterified product." The Petition relies on Cummings' disclosure of the OSI values of jojoba esters relative to refined jojoba oil. *See* Pet., 38 (citing Ex. 1004, 2). However, the Petition does not provide evidence that Cummings' jojoba esters are representative of the "transesterified product" as recited in claim 1.

51. Cummings describes that "[j]ojoba oil is converted to jojoba esters through a process known as interesterification." Ex. 1004, 2. However, Cummings does not describe that the jojoba esters for which an OSI value is provided (Ex. 1004, 2) are the transesterified product resulting from transesterification of a feedstock

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feedstock." Pet., 38 (emphasis added). However, as I describe in this section, the Petition does not explain the contributions of other feedstock components.

comprising the refined jojoba oil. Cummings does not specify the feedstock from which the jojoba esters are formed – whether it is the refined jojoba oil for which Cummings reports an OSI value or something else. The Petition does not provide any evidence or argument as to why Cummings' jojoba esters should be understood (or would have been understood by a POSITA) to be equivalent to the claimed transesterified product resulting from contacting the feedstock recited in claim 1. Without this, Cummings cannot provide a comparison between feedstock and transesterified product relevant to claim element [1c].

c) The Petition fails to demonstrate that it was well known that transesterification of jojoba oil results in products with higher OSI

52. The Petition fails to show that it was well known that transesterified products would have a higher OSI value than the feedstock from which they were produced. The Petition's statement that "it was well-known that the transesterification of fats, oils, and wax esters—including in lipase-catalyzed processes and processes involving jojoba wax esters and hydrogenated jojoba wax esters—can produce a product having improved, and thus greater, oxidative stability" is not supported by the references provided as allegedly corroborating the statement or the expert declaration. Pet., 38, 52, 58, 69.

53. As corroboration for this statement, the Petition cites to references describing transesterification of triglycerides or similar materials. *See* Pet., 38 (citing Ex. 1015, Ex. 1016, Ex. 1017, and Ex. 1018). But the Petition's cited references do not support

the claim that Cummings' OSI values given for refined jojoba oil and commercial jojoba esters meet the requirements of element [1c].

54. Kodali (Ex. 1015) describes "oils transesterified with short-chain fatty acid esters" and their lubrication properties. Ex. 1015, [0001]. Kodali transesterifies "short saturated fatty acid esters with triacylglycerol [i.e., triglycerides] containing oils" which "improves oxidative stability." *Id.*, [0005]. Kodali describes the oxidative stability and low temperature properties of transesterified vegetable oils in Table 1, but does not include or mention jojoba oils or jojoba wax esters. Kodali states that "the short chain fatty acid esters can be from six to 10 carbons in length." Ex. 1015, [0006]. Because jojoba esters are long chain esters, Kodali's description of the transesterification of short saturated fatty acid esters with triglycerol containing oils, is irrelevant to the claim element which requires transesterification of a feedstock including jojoba wax esters and hydrogenated jojoba wax esters. *See e.g.,* Ex. 1001, 6:65-66 ("The wax esters in jojoba oil generally vary between 34 and 48 carbons in length."); Ex. 1016, [0028] ("Jojoba oil is composed principally of 40 and 42 carbon chain esters, which are in turn composed of monounsaturated fatty acids and fatty alcohols of 20 and 22 carbon chain length"). Furthermore, Kodali's "vegetable oils are known to provide… low oxidative stability." Ex. 1015. Accordingly, the vegetable oils are distinguishable from jojoba oil, which is "highly resistant to oxidation" according to the Touitou reference cited in the Petition and

discussed below. Ex. 1016, [0028]. Kodali's description of the oxidative stability of vegetable oils do not reflect the chemical properties of jojoba oils. In addition to Kodali's lack of disclosure related to jojoba esters, Kodali also fails to describe the use of lipases in transesterification reactions.

55. Touitou (Ex. 1016) describes various dermatological compounds for preventing damage from UV radiation. Ex. 1016, Abstract. One compound described in Touitou is a "compound[] for topical application comprising at least one photoprotective compound for topical application comprising of hydroxylated derivatives of natural Jojoba wax/oil or its synthetic substitute, esterified with carboxylic acids or aminoacids [sic] bearing UV-absorbing groups." *Id.* Touitou describes that generally "Jojoba oil… [is] highly resistant to oxidation" (Ex. 1016, [0028]), and also that "Jojoba esters are… extremely resistant to oxidative degradation." *Id.*, [0031]. Accordingly, Touitou describes that both jojoba oil and jojoba esters have high oxidative stabilities, and does not provide any comparison of oxidation measures for feedstock and transesterified products nor refined jojoba oil. *Id.*, [0028].

56. Xu et al. (Ex. 1017, referred to as "Xu 2" herein) describes developments in lipid modification technologies including interesterification of triacylglycerols (e.g., triglycerides). Ex. 1017, 2. Xu 2 does not mention jojoba wax esters, and focuses on transesterification of triglycerides. Xu 2 describes that in studies involving

interesterification of triacylglycerols, the compounds "became more physically stable with [increasing conversion of the reaction]." *Id.*, 12. Based on these study results, Xu 2 suggests that "enzymatic interesterification has advantages for the oxidative stability of the products," but neglects to tie the results related to triglycerides to interesterified products involving other compounds. *Id.* Indeed, Xu 2's triglyceride-based experimental results are not relevant to jojoba oils because "[j]ojoba oil contains less than 3% triglyceride and [is] highly resistant to oxidation." Ex. 1016, [0028]. Xu 2's results related to oxidative stability of triglycerides are not applicable to jojoba oil because triglycerides are only present in trace amounts in jojoba oil. Xu 2 does not describe the oxidative stability of jojoba oils or wax esters, or provide experimental results relevant to oxidative stability advantages resulting from interesterification of jojoba oils or esters. Accordingly, Xu 2 fails to mention jojoba oil or wax esters, focuses on triglycerides, and does not provide OSI values for jojoba oils/esters or any other compounds for comparison.

57. Lopez-Hernandez (Ex. 1018) describes studies involving transesterification of triacylglycerols (e.g., triglycerides) and soybean oil. Ex. 1018, Abstract. Lopez-Hernandez discuss the use enzymatic reactions to interesterify a medium-chain triacylglycerol (MCT) oil with a soybean oil, and the "effects of the biocatalyst and the substrate mixture on the final TAG compositions and the corresponding melting profiles of the products." *Id*., 2. Lopez-Hernandez describes that in the resulting

compositions, "[t]he absence of unsaturated fatty acids residues [sic] implies that the products of the synthesis reaction have enhanced stability with regard to oxidation processes." *Id.*, 7. However, Lopez-Hernandez does not mention or describe experimental results using jojoba esters, and offers no OSI values for jojoba ester feedstocks or transesterified products which can be compared. Additionally, the Petition fails to provide any arguments that the results and conclusions of the Lopez-Hernandez article would be expected to hold true for jojoba wax esters.

58. The Petition also relies on Xu and *Trans* Isomers 2 as allegedly disclosing the use of lipases and enzymes in transesterification reactions. Both of Xu and *Trans* Isomers 2 also fail to provide any evidence that it was well known that use of a lipase to produce a transesterified product would result in a higher OSI value than an OSI value of the feedstock. Further, the Petition does not provide any analysis that would support a POSITA understanding this to be the case based on the Xu and *Trans* Isomers 2's disclosures.

59. These deficiencies demonstrate the Petition's failure to support its claim that it was well known that transesterification of jojoba wax esters and hydrogenated jojoba wax esters could produce products with greater oxidative stability. The Petition provides no evidence to support the contention that this was known.

60. Furthermore, Dr. Rockstraw's declaration similarly fails to provide any evidence to support the alleged obviousness of a transesterified product having a

greater OSI than the feedstock. Dr. Rockstraw's declaration fails to provide additional evidence to support the claim that it was well known that transesterified jojoba products would have a higher OSI value than the feedstock from which they were produced. *See* Ex. 1003, ¶¶122-123 (citing the same references as the Petition, each of which is described in detail above). Dr. Rockstraw points to general descriptions of jojoba esters as being "resistant to oxidative degradation" (Ex. 1016, [0031]) that lack any comparison between the OSI of a feedstock comprising (1) jojoba wax esters and (2) hydrogenated jojoba wax esters and a transesterified product produced by use of a lipase. Accordingly, the declaration fails to provide support for the Petition's claim that it was obvious that a transesterified product produced from a feedstock of jojoba wax esters and hydrogenated jojoba wax esters would have a higher OSI than the feedstock.

61. The Petition fails to point to any disclosure in Cummings equivalent to the claimed relationship of the OSI value between product and feedstock, and further does not show that the claimed relationship between the transesterified product and feedstock in [1c] is obvious. Accordingly, Cummings fails to teach or suggest that the claimed limitation of "an oxidative stability index (OSI) of [a] transesterified product [that] is greater than an OSI of the feedstock," where the "feedstock compris[es] jojoba wax esters and hydrogenated jojoba wax esters."

2. *Ground 2*

62. With regard to Ground 2, *Trans* Isomers 2 does not teach or suggest the claimed relationship "an oxidative stability index (OSI) of [a] transesterified product [that] is greater than an OSI of the feedstock [used as reactants of the transesterified product]." The Petition relies on *Trans* Isomers 2's description of a partially hydrogenated jojoba oil as the alleged feedstock, but fails to compare the OSI of the partially hydrogenated jojoba oil to a transesterification product of the alleged feedstock and does not account for the contributions of both "jojoba wax esters and hydrogenated jojoba wax esters" components of the feedstock. *See* Pet., 51. However, for the reasons described below, the Petition fails to show that *Trans* Isomers 2 teaches or suggests claim element [1c].

a) Trans Isomers 2 does not provide an OSI value of the "feedstock" and an increase in OSI from the feedstock to the transesterified product

63. In Ground 2, the Petition relies on *Trans* Isomers 2's description in Table 4 of OSI values for jojoba esters 30, jojoba esters 60, and jojoba oil partial hydrogenates as allegedly teaching the relationship of claim element [1c]. Pet., 51. Table 4 describes various material properties and characteristics of jojoba esters 30 and jojoba esters 60, and compares these properties to the properties of jojoba oil partial hydrogenate compounds having the same melting points as the jojoba esters. Ex. 1006, 3-4, Table 4, However, to the Petition does not show that the jojoba oil partial hydrogenate described in Table 4 is equivalent to the claimed feedstock.

TABLE 4. PHYSICAL PROPERTIES OF INTERESTERIFIED JOJOBA ESTERS IN COMPARISON WITH LIKE MELTING PARTIAL HYDROGENATES

Sample	Melting Point °C	Iodine Value g I₂/100g of Sample	% *Trans*	Oxidative Stability Index, Hours	Index of Refraction μD@80°C	Penetrometer, Mm	Slip, Cadicamo, Degress (1%)	Slip, IFT, Degress (100%)
Jojoba Esters 30	49	58	0	165	1.4418	26.4	18.9	23
Jojoba oil Partial Hydrogenate	49	69	11	27	1.4435	—	19.3	>25
Jojoba Esters 60	59	42	0	225	1.4403	9.3	17.9	14.1
Jojaba Oil Partial Hydrogenate	59	49	37	108	1.4408	5.2	18.1	15.4

Ex. 1006, Table 4.

64. First, the "jojoba oil partial hydrogenate" described in Table 4 is not described in *Trans* Isomers 2 as the feedstock from which the Jojoba Esters (30) and Jojoba Esters (60) are formed. Additionally, *Trans* Isomers 2 offers no description that would support Jojoba Esters (30) and Jojoba Esters (60) being transesterified products of the jojoba oil partial hydrogenate of Table 4. Neither the Petition nor Dr. Rockstraw's declaration provide any argument that would support such an assumption.

65. Instead, *Trans* Isomers 2 presents the jojoba oil partial hydrogenate as a product for ***comparison*** to the Jojoba Esters (30) and (60). Jojoba oil partial hydrogenate provides a useful comparison to the Jojoba Esters (30) and (60) products, because *Trans* Isomers 2 describes that "[p]artially hydrogenated jojoba oil can be shown to have trans isomers" while the Jojoba Esters products do not include trans isomers. Ex. 1006, 3. Thus, the jojoba oil partial hydrogenate is not a feedstock for a transesterification reaction that would result in the Jojoba Esters (30) and (60) products, but is instead a comparative product for demonstrating the characteristics of the Jojoba Esters products.

66. Because the Jojoba Esters (30) and (60) products are not produced from *Trans* Isomers 2's jojoba oil partial hydrogenate, the jojoba oil partial hydrogenate is not equivalent to the claimed feedstock of element [1c]. The Petition's comparison of the OSI values given for jojoba oil partial hydrogenate and Jojoba Esters (30) and (60) in *Trans* Isomers 2 fails to provide a comparison between a feedstock as claimed and a product.

67. Second, *Trans* Isomers 2 does not suggest that the jojoba oil partial hydrogenate includes both claimed feedstock components of (1) jojoba wax esters and (2) hydrogenated jojoba wax esters. Even if the jojoba oil partial hydrogenate were considered to represent the claimed feedstock (which is not conceded), the Petition does not demonstrate that the jojoba oil partial hydrogenate would include the two claimed components in the claimed weight percent ("wherein the amount of hydrogenated jojoba wax esters is 20 % to 50 % by weight of the feedstock"). *See* Ex. 1001, 19:12-14. The Petition does not point to any disclosure in *Trans* Isomers 2 indicating that the "Jojoba Oil Partial Hydrogenate" contains both jojoba wax esters and hydrogenated jojoba wax esters, let alone that it contains the recited amount of 20% to 50% as required by claim 1. Although variations in weight percent of the compounds contained in the feedstock would have an effect on the OSI value of the feedstock, the Petition does not given any explanation as to what those effects would be.

68. Accordingly, the Petition utterly fails to identify any disclosure in *Trans* Isomers 2 equivalent to the claimed relationship between product and feedstock in claim element [1c]. *Trans* Isomers 2 fails to teach or suggest the claimed limitation of "an oxidative stability index (OSI) of [a] transesterified product [that] is greater than an OSI of the feedstock," where the "feedstock compris[es] jojoba wax esters and hydrogenated jojoba wax esters."

b) Trans Isomers 2's Jojoba Esters 30 and Jojoba Esters 60 are not the claimed "transesterified product"

69. The Petition fails to provide evidence that *Trans* Isomers 2's Jojoba Esters 30 and 60 are representative of the "transesterified product" as recited in claim 1.

70. *Trans* Isomers 2 does not describe that Jojoba Esters (30) and (60) described in Table 4 are the transesterified product resulting from transesterification of a feedstock comprising the "Jojoba oil Partial Hydrogenate" also described in Table 4. *See* Ex. 1006, Table 4; *see also above* §V.A.2.a. *Trans* Isomers 2 does not specify the feedstock from which the Jojoba Esters (30) and (60) are formed. For example, there is no disclosure in *Trans* Isomers 2 that describes the feedstock for the Jojoba Esters (30) and (60) products as the "Jojoba oil Partial Hydrogenate" for which *Trans* Isomers 2 reports an OSI value. In fact, the jojoba oil partial hydrogenate is instead presented as a comparison product, and not a feedstock—and the Jojoba Esters (30) and (60) products would thus not be understood as transesterified products of the jojoba oil partial hydrogenate. Additionally, the Petition fails to

provide any evidence or argument as to why the Jojoba Esters 30 and 60 described in *Trans* Isomers 2 should be understood (or would have been understood by a POSITA) to be equivalent to the claimed transesterified product resulting from contacting the feedstock recited in claim 1.

c) The Petition fails to demonstrate that it was well known that transesterification of jojoba oil results in products with higher OSI

71. As in Ground 1, that the Petition also states in Ground 2 that "it was well-known that the transesterification of fats, oils and wax esters – including in lipase-catalyzed processes and processes involving jojoba wax esters and hydrogenated jojoba wax esters – can produce a product having improved, and thus greater, oxidative stability." Pet., 52. As discussed above, the claim that this relationship was well known lacks basis and is not supported by the references cited in the Petition or in Dr. Rockstraw's declaration. *See above* §V.A.1.c. For the same reasons discussed above, the Petition fails to provide support for the claim that it was well known that a transesterified jojoba ester product would have a higher OSI than the feedstock from which it was formed.

3. *Ground 3*

a) For the same reasons as in Ground 2, the Petition fails to demonstrate that Trans Isomers 2 teaches or suggests [1c]

72. In Ground 3, the Petition points to *Trans* Isomers 2 as allegedly disclosing or rendering obvious claim element [1c]. *See* Pet., 58. However, as described above,

the Petition fails to demonstrate (1) that the "Jojoba oil Partial Hydrogenate" described in *Trans* Isomers 2 is the claimed "feedstock," (2) that *Trans* Isomers 2 provides an OSI value of the "feedstock" and that there is an increase in OSI from the feedstock to the transesterified product; and (3) that Jojoba Esters 30 and Jojoba Esters 60 described in *Trans* Isomers 2 are equivalent the claimed "transesterified product." *See above* §§V.A.2.a-b. Additionally, for the same reasons discussed above in §V.A.2.c, *above*, the Petition fails to provide evidence that it was well known that a transesterified jojoba ester product would have a higher OSI than the feedstock fails as unsupported by the cited references. Accordingly, for the reasons explained above with regard to Ground 2, the Petition fails to show that *Trans* Isomers 2 teaches or suggests claim element [1c].

4. *Ground 4*

73. As discussed in the sections below, the deficiencies in Cummings' disclosure described above with regard to Ground 1 (*see above* §§V.A.1.a-c) are also present in Ground 4, where the Petition relies on Cummings's disclosure of element [1c]. In Ground 4, the Petition points to the combination of Brown and Cummings as disclosing limitation [1c], but relies on Cummings' disclosure of the OSI values of jojoba esters and jojoba oils as allegedly disclosing the increase in OSI value from the feedstock to the transesterified product. *See* Pet., 67-68. As described above with regard to Ground 1, the Petition does not show that Cummings teaches or

suggests the relationship of claim element [1c], and in Ground 4 Brown does not remedy these deficiencies.

a) Brown and Cummings do not provide an OSI value of the "feedstock" and an increase in OSI from the feedstock to the transesterified product

74. The Petition fails to show that either of Brown or Cummings teach or suggest a feedstock as claimed, or the OSI value of the transesterified product of the feedstock being greater than the OSI value of the feedstock itself. In Ground 4, the Petition states that "Brown discloses the transesterification of a feedstock of jojoba wax esters and hydrogenated jojoba esters to prepare jojoba esters." Pet., 67 (citing Ex. 1007, Abstract). While Brown describes that "[t]he compositions of the present invention may be obtained by a novel process of a base catalyzed alcoholysis reaction between jojoba oil and an alcohol" (Ex. 1007, Abstract), Brown does not provide any OSI value associated with jojoba oil or transesterified products of a jojoba oil feedstock. As in Ground 1, the Petition relies on Cummings' statement "[j]ojoba esters demonstrate remarkable stability with OSI values of all jojoba esters greater than 100 hours and as high as 675 hours… the OSI of refined jojoba is around 35 hours," as allegedly disclosing the claimed relationship of claim element [1c]. Ex. 1004, 2; *see also* Pet., 68. However, as described above in Ground 1, the Petition fails to provide proof that Cummings' refined jojoba oil is equivalent to the claimed feedstock containing "jojoba wax esters and hydrogenated jojoba wax esters." Similarly, the Petition fails to show that Brown's jojoba oil meets the claimed

feedstock containing "jojoba wax esters and hydrogenated jojoba wax esters." Accordingly, the Petition does not demonstrate that either of Brown or Cummings teach or suggest a compound equivalent to the claimed "feedstock."

75. Additionally, the Petition fails to provide arguments that the alleged jojoba oil "feedstock" described in Brown is equivalent to the "refined jojoba oil" for which Cummings provides an OSI value. Brown does not provide any OSI value associated with jojoba oil or transesterified products of a jojoba oil feedstock. Instead, the Petition relies on Cummings' statement that "[j]ojoba esters demonstrate remarkable stability with OSI values of all jojoba esters greater than 100 hours and as high as 675 hours… the OSI of refined jojoba is around 35 hours" as allegedly disclosing element [1c]. EX-1004, 2; *see also* Pet., 68. Accordingly, it is not clear that the OSI value described in Cummings is applicable to the alleged feedstock the Petition identifies in Brown. Neither Cummings nor Brown provide an OSI value associated with the alleged feedstock the Petition identifies in Brown.

76. As a result, the Petition fails to demonstrate that Cummings' discussion of the OSI of refined jojoba oil and OSI of jojoba esters is indicative of the claimed relationship of "the "oxidative stability index (OSI) of the transesterified product is greater than an OSI of the feedstock." Similarly, the Petition does not show that Brown, which as noted above is silent on OSI values associated with the feedstock, is relevant to the claimed relationship of claim element [1c].

b) Neither Brown's nor Cummings' jojoba wax esters are the claimed "transesterified product"

77. The Petition does not show that the jojoba wax esters described in either Brown or Cummings is equivalent to the claimed "transesterified product." The Petition concedes that Brown does not disclose transesterification of the feedstock by a lipase to produce a transesterified product in which an OSI is associated with the feedstock. *See* Pet., 66 ("Brown does not expressly disclose 'contacting the feedstock with a lipase'"). And, as described above, Cummings fails to describe that the jojoba esters for which an OSI value is provided are produced from the refined jojoba oil, and the Petition fails to provide any argument as to why a POSITA would have understood Cummings' jojoba esters to be a transesterified product of the refined jojoba oil for which Cummings provides an OSI value. *See above* §§V.A.1.a-b. Accordingly, not only do Cummings and Brown fail to provide an OSI value associated with the feedstock described by Brown, but neither reference provides an OSI value associated with the product of transesterification.

c) The Petition fails to demonstrate that it was well known that transesterification of jojoba oil results in products with higher OSI

78. As in Ground 1, in Ground 4 the Petition claims that "it was well-known that the transesterification of fats, oils and wax esters – including in lipase-catalyzed processes and processes involving jojoba wax esters and hydrogenated jojoba wax esters – can produce a product having improved, and thus greater, oxidative

stability." Pet., 52. As discussed above, the contention that this relationship was well known in jojoba esters lacks basis and is not supported by the references cited in the Petition and expert declaration. *See above* §V.A.1.c. For the same reasons discussed above, the Petition fails to support the claim that it was well known that a transesterified jojoba ester product would have a higher OSI than the feedstock.

B. The Proposed Grounds Fail to Provide "the Amount of Hydrogenated Jojoba Wax Esters is 20% to 50% by Weight of the Feedstock"

79. The Petition fails to show that a POSITA would have found it obvious to "provid[e] a feedstock comprising jojoba wax esters and hydrogenated jojoba wax esters, wherein the amount of hydrogenated jojoba wax esters is 20 % to 50 % by weight of the feedstock" before the Critical Date. In each of Grounds 1-4, the Petition acknowledges that the primary reference fails to expressly disclose a feedstock including jojoba wax esters and hydrogenated jojoba wax esters in the claimed weight percent, and instead relies on a back-calculation of the weight of the reactants from an iodine value ("IV") given for various commercial jojoba ester products. However, this back-calculated estimate is neither clear nor accurate for determining a weight percent of a reactant.

80. Additionally, the Petition's reliance in the alternative on the combination of each primary reference with Sessa in Grounds 1-4 is deficient as neither Sessa nor

the Petition provides a clear motivation for modifying the primary reference to achieve the particular claimed weight percentages of claim element [1a].

81. Accordingly, as I will describe further below, the Petition fails to demonstrate that the prior art teaches or suggests claim element [1a].

1. *Ground 1*

a) Cummings does not disclose a feedstock in which the "amount of hydrogenated jojoba wax esters is 20% to 50% by weight"

82. In Ground 1, the Petition concedes that "Cummings does not expressly disclose '20% to 50%' in specific words." Pet., 29. (Emphasis omitted). Indeed, Cummings does not provide any description of the weight percentages of reactants contained in a feedstock used in producing the various commercial jojoba esters described in Fig. 3.

83. Accordingly, Cummings does not disclose the claimed feedstock in which an "amount of hydrogenated jojoba wax esters is 20% to 50% by weight."

b) The Petition's back-calculation of reactant weight percentages from the iodine value is not an accurate estimation

84. The Petition's reliance on a back-calculation of weight percentages of reactants in a feedstock based on iodine values of various jojoba ester products is misplaced because the back-calculation relies on multiple unfounded assumptions and does not provide an accurate estimate. The Petition alleges that although Cummings fails to disclose the weight percent of hydrogenated jojoba wax esters

recited in [1a], a POSITA would have understood Cummings' disclosure of iodine values of various jojoba ester products to teach the claimed weight range. *See* Pet., 29-35. However, the Petition's attempts to estimate the weight of the reactants based on an alleged correlation between an iodine value and the number of double bonds present in the product fails for multiple reasons.

85. First, the equation derived in Dr. Rockstraw's declaration and used in the Petition in the back-calculation of weight percentages of reactants appears to be incorrect. As an initial matter, Dr. Rockstraw points to a publication of the American Oil Chemists' Society (Ex. 1025) and a textbook related to Fat and Oil formulation (Ex. 1026) as allegedly providing the starting point for the derived equations. *See* Ex. 1003, ¶102. These references describe formulas for calculating an IV of a fatty acid or fatty acid blend – not for deriving the components of a fatty acid blend from an IV, and definitely not for deriving components of a fatty acid blend feedstock from the IV of a transesterified product of the fatty acid blend. Next, Dr. Rockstraw's equation given in paragraph 104 appears to be incorrectly derived, as the use of the equation with the iodine values given in Cummings and *Trans* Isomers 2 results in negative values—of course, negative weight percent values would not make sense.

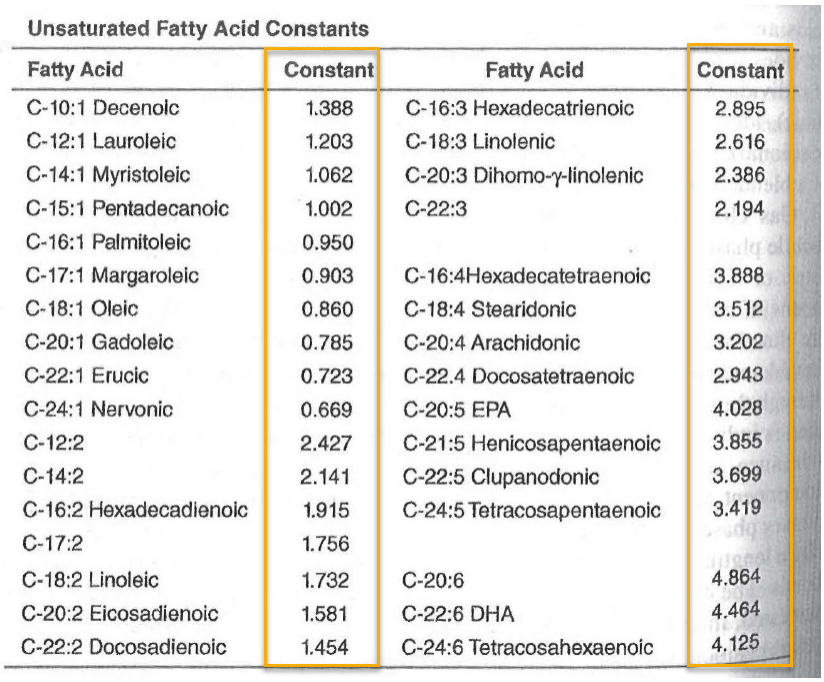
86. Even worse, the American Oil Chemists' Society publication (Ex. 1025) and Fat and Oil formulation textbook (Ex. 1026) each refer to a method for calculation

of the iodine value using a factor or constant that is specific to a known fatty acid (or triglyceride). *See* Ex. 1026, 3 ("The constants for the most common unsaturated fatty acids required for calculation of a triglyceride iodine value are shown below"); Ex. 1025, 3 (showing Table 1 including columns for triglyceride factors and fatty acid factors). As illustrated below in the Tables reproduced from these exhibits, the additional factor or constant depends on the particular fatty acid, and can range in value such that omission of these factors would have a meaningful impact on the calculated iodine value.

Table 1
Conversion factors for triglycerides and free fatty acids

	MW Triglyceride	I	I M.W. 126.9045	Factor Triglyceride	MW Fatty Acid	I	I M.W. 126.9045	Factor Fatty Acid
C12:1	633.01	6	761.4270	1.2029	198.3500	2	253.8090	1.2796
C14:1	717.18	6	761.4270	1.0617	226.3800	2	253.8090	1.1212
C15:1 *trans*	759.16	6	761.4270	1.0030	240.4000	2	253.8090	1.0558
C15:1	759.16	6	761.4270	1.0030	240.4000	2	253.8090	1.0558
C16:1 *trans*	801.34	6	761.4270	0.9502	254.4300	2	253.8090	0.9976
C16:1	801.34	6	761.4270	0.9502	254.4300	2	253.8090	0.9976
C17:1 *trans*	843.42	6	761.4270	0.9028	268.4800	2	253.8090	0.9454
C17:1	843.42	6	761.4270	0.9028	268.4800	2	253.8090	0.9454
C18:1 *trans*	885.50	6	761.4270	0.8599	282.4800	2	253.8090	0.8985
C18:1	885.50	6	761.4270	0.8599	282.4800	2	253.8090	0.8985
C18:2 *trans*	879.50	12	1522.8540	1.7315	280.4800	4	507.6180	1.8098
C18:2	879.50	12	1522.8540	1.7315	280.4800	4	507.6180	1.8098
C18:2 CLA	879.50	12	1522.8540	1.7315	280.4800	6	507.6180	1.8098
C18:3 *trans*	873.50	18	2284.2810	2.6151	278.4800	6	761.4270	2.7342
C18:3	873.50	18	2284.2810	2.6151	278.4800	6	761.4270	2.7342
C20:1	969.66	6	761.4270	0.7853	310.5400	2	253.8090	0.8173

Ex. 1025, Table 1 (yellow boxes added to highlight factors).



Unsaturated Fatty Acid Constants

Fatty Acid	Constant	Fatty Acid	Constant
C-10:1 Decenoic	1.388	C-16:3 Hexadecatrienoic	2.895
C-12:1 Lauroleic	1.203	C-18:3 Linolenic	2.616
C-14:1 Myristoleic	1.062	C-20:3 Dihomo-γ-linolenic	2.386
C-15:1 Pentadecanoic	1.002	C-22:3	2.194
C-16:1 Palmitoleic	0.950		
C-17:1 Margaroleic	0.903	C-16:4Hexadecatetraenoic	3.888
C-18:1 Oleic	0.860	C-18:4 Stearidonic	3.512
C-20:1 Gadoleic	0.785	C-20:4 Arachidonic	3.202
C-22:1 Erucic	0.723	C-22.4 Docosatetraenoic	2.943
C-24:1 Nervonic	0.669	C-20:5 EPA	4.028
C-12:2	2.427	C-21:5 Henicosapentaenoic	3.855
C-14:2	2.141	C-22:5 Clupanodonic	3.699
C-16:2 Hexadecadienoic	1.915	C-24:5 Tetracosapentaenoic	3.419
C-17:2	1.756		
C-18:2 Linoleic	1.732	C-20:6	4.864
C-20:2 Eicosadienoic	1.581	C-22:6 DHA	4.464
C-22:2 Docosadienoic	1.454	C-24:6 Tetracosahexaenoic	4.125

Ex. 1026, 3 (yellow boxes added to highlight factors).

The references that Dr. Rockstraw relies on in supporting the equation derived for the back-calculation of reactant weight percentages identify factors for each fatty acid component that are critical for the determination of an iodine value, but none of those factors are included or accounted for in the equations presented in Dr. Rockstraw's declaration. *See* Ex. 1003, ¶¶102-104. This further suggests that the equation used in calculating the reactant weight percentages from the iodine value of the blend may be incomplete and the calculated results may not be accurate.

87. Second, the Petition fails to establish that what the actual compositions of the Jojoba esters "products" are and therefore cannot correlate the products' iodine value to its feedstock. The iodine values reported by Cummings are associated with commercial jojoba ester products following transesterification. *See* Ex. 1004, Fig.

3. Back-calculation of the weight percentages of the original feedstock components (i.e., the reactants) from this value mistakenly relies on multiple assumptions about the products and the compounds that might form the feedstocks from which the products are formed.

88. Iodine value is not intended to provide information about the contents of a feedstock from which a product is formed – it is most commonly used to monitor the progress of a reaction. Iodine value is a measure of total saturation or unsaturation of an oil or fat. *See* Ex. 2002, 1, 2. "IV has been included in the standards of some industrial products derived from vegetable oils and fats, such as biodiesel [and i]t is also occasionally used in assessing oxidative stability of oils and fats and their derivatives." *Id.*, 1. The theoretical iodine value of a pure compound can be calculated based on the molecular weight of the compound and the number of double bonds present in the compound (because the iodine atoms are added to each double bond in the wet chemical method for determining IV). *Id.*, 2.

89. Cummings does not describe the transesterification processing methods used to produce the jojoba esters and corresponding yields, and, as a result, it is not possible to assess whether the products are reflective of actual reaction products of a transesterification process. For example, does "Jojoba esters (30)" reflect a product that contains only desired ester compositions as shown in Fig. 2 of Cummings? Or does "Jojoba esters (30)" also include side-products or unreacted

feedstock, as might be expected in a chemical transesterification process? Or is "Jojoba esters (30)" subjected to post-reaction refining processes that further purify the esters contained in the "product"? Any of these or other scenarios related to the contents of the Jojoba esters product could impact the iodine value of the "Jojoba esters (30)" product by changing the binding of the iodine to the double bonds or providing additional products that interact with the iodine, for example. Accordingly any of these scenarios could impact the estimated weight percent of the reactants estimated by the back-calculation. Multiple questions exist, the answers to which are highly relevant to the back-calculation proposed by the Petition, and these questions are unanswered by Cummings or the Petition. Because the answers to these questions about the contents of the product would significantly affect whether one can establish any conclusions about the reaction product, as well as its reactants (e.g., feedstock), the Petition's back-calculation of weight percentages of the reactants based on the iodine value of the "product" cannot be relied upon. *See* Ex. 2002, 1 ("structure indices [such as iodine value] of fatty compounds can be influenced by the presence of accompanying materials…. as these indices often depend on the amounts of all components of a mixture."). Because the Petition fails to establish what the full composition of each Jojoba ester product listed in Figure 3 is, it is not possible to know the weight percentages of the reactants based on the product's iodine values.

90. Third, the back-calculation relies on the assumption that all jojoba esters resulting from the transesterification are either fully saturated or fully unsaturated, and that the ratios/weights of these wax esters relative to one another are unchanged by the transesterification process. *See* Pet., 30. However, contrary to Petition's assertions otherwise, Cummings describes that this is not necessarily the case: "Interesterification produces jojoba esters engineered to contain different ratios of molecules with either no double bonds (fully saturated), one double bond (monounsaturated) or two double bonds (fully unsaturated)… It is these compositional differences … that create their expanded utility in cosmetic preparations." EX-1004, 2. If, as Cummings reports, the ratio of fully saturated jojoba wax esters can be changed by the transesterification process, the final ratio may not be indicative of the starting amounts or percentages of the reactants. Neither Cummings nor the Petition provide any reason to treat the composition of the final jojoba ester products as representative of the original materials.

91. Finally, the Petition's back-calculation neglects to consider the impact of other factors on the iodine value of a product. "The IV of higher esters decrease with increasing size of the alcohol moiety [as a] result of the IV being dependent on the M.W. [molecular weight] of the fatty compound." Ex. 2002, 2. While the iodine value of a pure compound may be calculated based on knowledge of the molecular weight and the number of double bonds present, back-calculation of the reactants

from an iodine value of a product is not so straight-forward as the Petition makes out.

92. "[A] given IV can be satisfied with different FA [fatty acid] profiles." Ex. 2002, 3. This is a result of the IV of a mixture of fatty compounds being dependent on the amounts of the fatty components of the mixture "but not on the exact nature of the double bonds in the structure of those fatty components." *Id.* A given iodine value can be reached by multiple compositions of a set of fatty acids, and by multiple combinations of various fatty acids. This, along with the lack of information about the products themselves, makes the estimation of weight percentages of the reactants by back-calculation from IV imprecise at best. *See also* Ex. 2002, 2 ("Many wet chemical methods for determining IV and SV have limited applicability and/or are error-prone as stated in remarks that accompany these methods").

93. The Petition fails to address the actual compositions of the jojoba ester products relative to the reactants, and instead relies on a method of back-calculation to estimate the weight percent of the reactants without accounting for the assumptions underlying the use of iodine value in this estimation. This reliance on the back-calculation to determine the weight percent of the reactants is inaccurate and based on untenable assumptions.

c) Cummings in view of Sessa do not teach or suggest a feedstock in which the "amount of hydrogenated jojoba wax esters is 20% to 50% by weight"

94. The Petition's alternative reliance on Sessa does not remedy the deficiencies of Cummings with regard to claim element [1a]. In the alternative, the Petition points to Sessa in combination with Cummings as allegedly teaching or suggesting claim element [1a]. The Petition states that "a POSA would have found it obvious to modify the process disclosed in Cummings to include 20% to 50% by weight of hydrogenated jojoba wax esters in the feedstock, as disclosed in Sessa." Pet., 30-31. However, Sessa's description of a calibration set of jojoba wax ester blends for use in producing compositions with thermal properties mimicking those of cocoa butter is disconnected from Cummings, and the Petition does not provide reasons that would have motivated a POSITA to make the proposed the combination. *See* Ex. 1009, 1.

95. The Petition fails to demonstrate that a POSITA would have been motivated to use Sessa's calibration set of jojoba wax ester blends in preparing a feedstock for the preparation of the jojoba esters described in Cummings. The Petition states that "[a] POSA would have been motivated—and found it routine optimization—to vary the amount of hydrogenated jojoba wax esters in the feedstock disclosed in Cummings to an amount that is 20% to 50% by weight of the feedstock, as disclosed in Sessa, to obtain desirable and/or improved physical properties, such as oxidative stability and thermal properties in the transesterified product, and would have had a

reasonable expectation of success in so doing." Pet., 33-34. However, the Petition does not provide any analysis as to why a POSITA would have been motivated to look to or incorporate Sessa's calibration set of jojoba esters in Cummings' feedstock for producing jojoba esters. Further, the Petition fails to explain why a POSITA would have modified Cummings with Sessa's calibration set to achieve the claimed weight percentages. Given that Sessa's aim is to provide "a cocoa butter equivalent," it is not clear why a POSITA would have modified Cummings to incorporate the calibration set to achieve the claimed weight percentages, and the Petition provides no analysis or rationale to fill this gap.

2. *Ground 2*

a) Trans Isomers 2 does not disclose a feedstock in which the "amount of hydrogenated jojoba wax esters is 20% to 50% by weight"

96. In Ground 2, the Petition concedes that "*Trans* Isomers 2 does not expressly disclose '20% to 50%.'" Pet., 44. (Emphasis omitted). Indeed, *Trans* Isomers 2 does not provide any description of the reactant amounts in a feedstock for preparing the various commercial jojoba esters described in Table 2. Ex. 1006, 3, Table 2.

97. Accordingly, *Trans* Isomers 2 does not disclose the claimed feedstock in which an "amount of hydrogenated jojoba wax esters is 20% to 50% by weight."

b) The Petition's back-calculation of reactant weight percentages from the iodine value is not an accurate estimation

98. As in Ground 1 above, the Petition improperly relies on an estimate of the weight percentages of the reactants based on a back-calculation from the iodine values associated with various jojoba esters for claim element [1a]. As described above, the Petition's reliance on the back-calculation from iodine values is inaccurate, at least because (1) the Petition does not establish that what the actual compositions of the Jojoba esters "products" are and therefore cannot correlate the products' iodine value to its feedstock; (2) the Petition's calculation relies on an equation which may be incorrectly derived and inaccurate, and further relies on the assumption that all jojoba esters resulting from the transesterification are either fully saturated or fully unsaturated, and that the ratios/weights of these wax esters relative to one another are unchanged by the transesterification process, which the Petition has not demonstrated is necessarily true; and (3) the Petition's back-calculation neglects to consider the impact of other factors on the IV of a product. *See above* §V.B.1.b. Accordingly, for the reasons explained above with regard to Ground 1, the Petition does not show that *Trans* Isomer's 2 teaches or suggests claim element [1a] in Ground 2.

c) Trans Isomers 2 in view of Sessa does not teach or suggest a feedstock in which the "amount of hydrogenated jojoba wax esters is 20% to 50% by weight"

99. As in Ground 1 above, the Petition's alternative reliance on Sessa does not remedy the deficiencies of *Trans* Isomers 2 with regard to claim element [1a]. The Petition presents an alternative ground which relies on the disclosure of Sessa as purportedly providing the claimed weight percent of the feedstock. *See* Pet., 46. However, the Petition fails to demonstrate that a POSITA would have been motivated to use Sessa's calibration set of jojoba wax ester blends in preparing a feedstock for the preparation of the jojoba esters described in *Trans* Isomers 2. In support of the proposed combination, the Petition merely lists the same alleged motivations for the combination of Sessa with *Trans* Isomers 2 as were listed as motivations for the combination of Sessa with Cummings in Ground 1. *Id.*, 46-47; *see also id.*, 33-34. These motivations are no more compelling with regard to the combination of Sessa with *Trans* Isomers 2 than they were in Ground 1. The Petition does not provide any analysis as to why a POSITA would have been motivated to look to or incorporate Sessa's calibration set of jojoba esters for providing "a cocoa butter equivalent" in *Trans* Isomers 2's feedstock for producing jojoba esters, much less why a POSITA would have modified *Trans* Isomers 2 with Sessa's calibration set to achieve the claimed weight percentages.

3. *Ground 3*

a) The Petition fails to show that **Trans** *Isomers 2, alone or in combination with Sessa, teaches or suggests claim element [1a]*

100. In Ground 3, as in Ground 2 described above, the Petition fails to (1) provide evidence that *Trans* Isomers 2 discloses the claimed weight percentage of [1a]; (2) demonstrate that back-calculation of reactant weight percentages from the iodine value of a product is an accurate estimation; and (3) demonstrate that *Trans* Isomers 2 in view of Sessa render obvious a feedstock in which the "amount of hydrogenated jojoba wax esters is 20% to 50% by weight" in view of Sessa's discussion of jojoba calibration sets for producing a cocoa butter alternative. *See above* §§V.B.2.a-c. Accordingly, for the reasons explained above with regard to Ground 2, the Petition has failed to show that *Trans* Isomers 2, alone or in combination with Sessa, teaches or suggests claim element [1a].

4. *Ground 4*

a) Brown does not disclose a feedstock in which the "amount of hydrogenated jojoba wax esters is 20% to 50% by weight"

101. In Ground 4, the Petition concedes that "Brown does not expressly disclose '20% to 50%.'" Pet., 61-62. (Emphasis omitted). Indeed, Brown does not provide any description of the reactant amounts in a feedstock for preparing the various commercial jojoba esters ("Floraesters") described. Ex. 1008, 8:45-54.

102. Accordingly, Brown does not disclose the claimed feedstock in which an "amount of hydrogenated jojoba wax esters is 20% to 50% by weight."

b) The Petition's back-calculation of reactant weight percentages from the iodine value is not an accurate estimation

103. As in Ground 1 above, the Petition improperly relies on an estimate of the weight percentages of the reactants based on a back-calculation from the iodine values associated with various jojoba esters to meet element [1a]. As described above, the Petition's reliance on the back-calculation from iodine values is inaccurate, at least because (1) the Petition fails to establish that what the actual compositions of the Jojoba esters "products" are and therefore cannot correlate the products' iodine value to its feedstock; (2) the calculation relies on an equation which may be incorrectly derived and inaccurate, and further relies on the assumption that all jojoba esters resulting from the transesterification are either fully saturated or fully unsaturated, and that the ratios/weights of these wax esters relative to one another are unchanged by the transesterification process, which the Petition has not demonstrated is necessarily true; and (3) the back-calculation neglects to consider the impact of other factors on the IV of a product. *See above* §§V.B.1.a-c.

104. Accordingly, for the reasons explained above with regard to Ground 1, the Petition has failed to show that Brown teaches or suggests claim element [1a] in Ground 4.

c) Brown in view of Sessa does not teach or suggest a feedstock in which the "amount of hydrogenated jojoba wax esters is 20% to 50% by weight"

105. As in Ground 1 above, the Petition's alternative reliance on Sessa does not remedy the deficiencies of Brown with regard to claim element [1a]. The Petition presents an alternative ground which relies on the disclosure of Sessa as purportedly providing the claimed weight percent of the feedstock. *See* Pet., 63. As described above, the Petition does not show that a POSITA would have been motivated to use Sessa's calibration set of jojoba wax ester blends in preparing a feedstock for the preparation of the jojoba esters described in Brown. In support of the proposed combination of Brown and Sessa in Ground 4, the Petition merely lists the same alleged motivations as were listed as motivations for the combination of Sessa with Cummings in Ground 1. *Id.*, 64-65; *see also id.*, 33-34. These motivations are no more compelling with regard to the combination of Sessa with Brown than they were in Ground 1. The Petition provides no analysis as to why a POSITA would have been motivated to look to or incorporate Sessa's calibration set of jojoba esters for providing "a cocoa butter equivalent" in Brown's feedstock for producing Floraesters, much less why a POSITA would have modified Brown with Sessa's calibration set to achieve the claimed weight percentages.

VI. LEGAL STANDARDS

A. Terminology

106. I have been informed by Counsel and understand that the best indicator of claim meaning is its usage in the context of the patent specification as understood by one of ordinary skill. I further understand that the words of the claims should be given their plain meaning unless that meaning is inconsistent with the patent specification or the patent's history of examination before the Patent Office. Counsel has also informed me, and I understand that, the words of the claims should be interpreted as they would have been interpreted by one of ordinary skill at the time of the invention was made (not today). Because I do not know at what date the invention as claimed was made, I have used the earliest possible priority date of the '245 Patent as the point in time for claim interpretation purposes (the Critical Date).

B. Legal Standards for Anticipation

107. I have been informed by Counsel and understand that documents and materials that qualify as prior art can render a patent claim unpatentable as anticipated. I have been informed by Counsel and understand that all prior art references are to be looked at from the viewpoint of a person of ordinary skill in the art.

108. I have been informed by Counsel and understand that a challenged claim is unpatentable as "anticipated" under 35 U.S.C. § 102 if it is determined that all the

limitations of the claim are described in a single prior art reference. I have been informed by Counsel and understand that, to anticipate a claim, a prior art reference must disclose, either expressly or inherently, each and every limitation of that claim and enable one of ordinary skill in the art to make and use the invention.

109. I have been informed by Counsel and understand that in an *inter partes* review, "the petitioner shall have the burden of proving a proposition of unpatentability," including a proposition of anticipation, "by a preponderance of the evidence." 35 U.S.C. §316(e).

C. Legal Standards for Obviousness

110. I have been informed by Counsel and understand that documents and materials that qualify as prior art can render a patent claim unpatentable as obvious. I have been informed by Counsel and understand that all prior art references are to be looked at from the viewpoint of a person of ordinary skill in the art at the time of the invention, and that this viewpoint prevents one from using his or her own insight or hindsight in deciding whether a claim is obvious.

111. I have been informed by Counsel and understand that a claim is unpatentable for obviousness under 35 U.S.C. § 103 "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." I have been informed

by Counsel and understand that obviousness may be based upon a combination of references. I have been informed by Counsel and understand that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. However, I have been informed by Counsel and understand that a patent claim composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

112. I have been informed by Counsel and understand that when a patented invention is a combination of known elements, a court must determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue by considering the teachings of prior art references, the effects of demands known to people working in the field or present in the marketplace, and the background knowledge possessed by a person having ordinary skill in the art.

113. I have been informed by Counsel and understand that a patent claim composed of several limitations is not proved obvious merely by demonstrating that each of its limitations was independently known in the prior art. I have been informed by counsel for the Patent Owner and understand that identifying a reason those elements would be combined can be important because inventions in many instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known. I have been informed

by Counsel and understand that it is improper to use hindsight in an obviousness analysis, and that a patent's claims should not be used as a "roadmap."

114. I have been informed by Counsel and understand that an obviousness inquiry requires consideration of the following factors: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) any objective indicia of non-obviousness, such as commercial success, long-felt but unresolved need, failure of others, industry recognition, copying, and unexpected results. I understand that the foregoing factors are sometimes referred to as the "Graham factors."

115. I have been informed by Counsel and understand that an obviousness evaluation can be based on a combination of multiple prior art references. I understand that the prior art references themselves may provide a suggestion, motivation, or reason to combine, but that the nexus linking two or more prior art references is sometimes simple common sense. I have been informed by Counsel and understand that obviousness analysis recognizes that market demand, rather than scientific literature, often drives innovation, and that a motivation to combine references may be supplied by the direction of the marketplace.

116. I have been informed by Counsel and understand that if a technique has been used to improve one device, and a person of ordinary skill at the time of invention

would have recognized that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

117. I have been informed by Counsel and understand that practical and common sense considerations should guide a proper obviousness analysis, because familiar items may have obvious uses beyond their primary purposes. I have been informed by Counsel and understand that a person of ordinary skill looking to overcome a problem will often be able to fit together the teachings of multiple prior art references. I have been informed by Counsel and understand that obviousness analysis therefore takes into account the inferences and creative steps that a person of ordinary skill would have employed at the time of invention.

118. I have been informed by Counsel and understand that a proper obviousness analysis focuses on what was known or obvious to a person of ordinary skill at the time of invention, not just the patentee. Accordingly, I understand that any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.

119. I have been informed by Counsel and understand that a claim can be obvious in light of a single reference, without the need to combine references, if the elements of the claim that are not found explicitly or inherently in the reference can be supplied by the common sense of one of skill in the art.

120. I have been informed by Counsel and understand that secondary indicia of non-obviousness may include (1) a long felt but unmet need in the prior art that was satisfied by the invention of the patent; (2) commercial success of processes covered by the patent; (3) unexpected results achieved by the invention; (4) praise of the invention by others skilled in the art; (5) taking of licenses under the patent by others; (6) deliberate copying of the invention; (7) failure of others to find a solution to the long felt need; and (8) skepticism by experts. I understand that evidence of secondary indicia of non-obviousness, if available, should be considered as part of the obviousness analysis.

121. I have been informed by Counsel and understand that there must be a relationship between any such secondary considerations and the invention, and that contemporaneous and independent invention by others is a secondary consideration supporting an obviousness determination.

122. In sum, my understanding is that prior art teachings are properly combined where one of ordinary skill having the understanding and knowledge reflected in the prior art and motivated by the general problem facing the inventor, would have been led to make the combination of elements recited in the claims. Under this analysis, the prior art references themselves, or any need or problem known in the field of endeavor at the time of the invention, can provide a reason for combining the elements of multiple prior art references in the claimed manner.

123. I have been informed by Counsel and understand that in an *inter partes* review, "the petitioner shall have the burden of proving a proposition of unpatentability," including a proposition of obviousness, "by a preponderance of the evidence." 35 U.S.C. §316(e).

VII. CONCLUSION

124. I reserve the right to supplement my opinions to address any information obtained, or positions taken, based on any new information introduced throughout this proceeding.

125. I declare under penalty of perjury that the foregoing is true and accurate to the best of my ability.

APPENDIX A

Thomas M. Schultz, Ph.D.
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CAREER SUMMARY: A proven Fast Moving Consumer Goods Executive with successes in building new technology and business teams. Dr. Schultz has held senior executive positions in Technology Leadership, Research and Innovation, and New Business Development for Bristol-Myers Squibb, Procter & Gamble, Shiseido, L'Oreal, Playtex Products, Inc, and DuPont de Nemours and other global companies. He has a strong record of new product development enabled on the strategy that cross-functional teams of R&D, marketing and commercial functions builds strong brands and the growth companies require, adding income growth in the 25% range driven by a significant number of brand-recognized new entries.

Credentials include a Ph.D. in Physical-Organic Chemistry in Chemotherapeutics (New York University), Executive Diploma in Business Administration (INSEAD, France), and Board experience (Public/Private). An inventor on more than 40 patents, presenter and author of scientific papers and served on various industry association boards (Personal Care Products Council, the Scientific Advisory Council Executive Research Board, The Da Vinci Charter Schools (Los Angeles, CA, and others). Poly-lingual, an excellent public speaker on the subjects of product innovation, technology mining, and coordinating consumer insights successfully into the invention stream of product development in the EU, China, Japan and the US.

Consulting experience includes litigation support as a subject matter expert in intellectual property assessment, including patent infringement damages estimations; new materials opportunity development and new product market programs. Prior a Partner with Horizon Partners Ventures LLC (2011-2021) that focused on de-risking new initiative investments for private equity and venture capital clients and leading initiatives funded by the state of Delaware. He was Client Leader (Part Owner) for Baker Street Solutions LLC (2009-2012), a boutique consultancy to personal and home care and the OTC major brands on innovation processes, business strategy and implementation of best practices as a contractor for Big 5 consulting firms. From 2005 though 2008, Dr. Schultz was SVP/CTO of Playtex Products (Energizer Holdings) including new product initiatives for all brands (Wet Ones, Playtex Fem-Care, Infant Products, Banana Boat and Hawaiian Tropic Sun Care) and the technology M&A due diligence/integration for the acquisition of Hawaiian Tropic. ENR and PYX is the largest contract manufacturer of PVL sun care products. From 2002-2005 President, E.I. DuPont Aspect LLC division in the personal and home care and dermatology markets. He also led business development, technology and R&D in the internet CPG/personal care space as Director of Personal Care Products at Proctor and Gamble, 1999 to 2002; Private Equity placement as Interim VP R&D at NuSkin Inc. (2003). Global AVP of Hair and Skin Technology at L'Oreal (1992-1997). From 1984-1992 Clairol and Shiseido R&D leadership.

CAREER DETAILS

Horizon Partners Ventures LLC, Partner, 2012 to 2021*; Medical and MaterialsTechnology commercialization, Delaware.* Identified new technologies and brings to commercialization or other monetization end states.

Baker Street Laboratories, Client Leader *2009-2012; New Initiatives and Consumer Products, New York, NY and San Francisco, CA.*
Developed Top-line Revenue, Innovation Processes, New Business Development, and implementation of best practices to companies across all consumer products, medical device, OTC drugs, banking and media markets. Clientele included Big 4 consulting and Global Fortune 500 consumer products companies.

Energizer Holdings, Inc., Senior Vice-President-Chief Technical Officer*, RD&E /QA (Playtex Products Division), Westport, CT and Allendale, NJ. 2005 -2009.*
Executive Team member reporting to the CEO to build new products and technologies globally. Led Global RD&E and Quality Assurance/Control needs of the company; established a China-based RD&E and Innovation center, Led technology part of M&A due diligence for the acquisition of the Hawaiian Tropic sun care and EU-based Jeyes companies

Interim Executive Assignment; NuSkin Enterprises, Vice President, Technology, RD&E, QA & Supply Chain; *2004-2005* Provo, UT
Recruited by CEO of international $1.1BN multi-level marketing business to design a dermatology initiative and consolidate its personal care and pharmaceutical supply chain and technology development organizations.

E.I. DuPont de Nemours, Inc., **President**- ***Aspect-LLC Division****;* Business & Technology Development, *Wilmington, Delaware 2002-2004.*
Recruited in to leverage out DuPont technologies. Reported to SVP-Chief Technology Officer. Led organization to re-purpose biotechnologies and chemicals into higher-value applications in the personal/ home care and OTC (dermatology) markets and the sale of the business to COGNIS Chemicals (Germany).

Procter & Gamble, Director*, Personal Care Products (reflect.com Division), San Francisco, CA, 1999-2002* Built and led the creation of P&G's mass customization personal care product process including all FDA requirements and supply chain logistics.

L'Oreal, Inc., ASSISTANT VICE PRESIDENT, TECHNOLOGY *International Personal Care, Clark, NJ and Paris, France 1992-1998*

Shiseido, Ltd., VICE PRESIDENT, RESEARCH AND DEVELOPMENT*,* (ZOTOS Division), Biotechnology *and Consumer Products, Darien, CT and Tokyo, Japan, 1988-1992* Oversight of US and EU laboratories including, Product, Regulatory, Safety and Technology Development, laboratory consolidation, government / industry contact for U.S., Europe and Japan. Involved in M&A activities.

Clairol, Inc, GROUP MANAGER, HAIR CARE R&D, Stamford CT., *1983-1988*
Directed hair care R&D and product Development for hair color brands.

Education & Professional Associations

- ***INSEAD***, Fontainebleau, France – Executive Course Business Management (1996)
- **NEW YORK UNIVERSITY** - Ph.D., Physical Organic Chemistry (1984)
- **NEW YORK UNIVERSITY** - MS, Chemistry (1979)
- **NEW YORK UNIVERSITY** - BA, Russian Languages / Chemistry-Physics (1977)

- **American Chemical Society**- Retired General Member
- **Product Development & Manufacturers Association**- Past General Member
- **Society Of Gynecological Research**- Past Executive Board Member, expired,
- **Executive Research Council** – Technology Executive Committee, consulting member
- **Personal Care Products Council**- Scientific Advisory Council- consulting member

Board Functions:
Past Board of Directors, *The DaVinci Schools;* Los Angeles County Charter School Initiative; retired
Past Board of Advisors- QED Program, *The City University Science Center,* Philadelphia, PA; as needed

Languages: English, Russian, French, Conversational Spanish, German, and Japanese

Litigation Experience: **Cases upon request**; Subject Matter Expert (Patent Infringement, Damages from Infringement, Product Development-Personal and Home Care, Medical Devices I & II, OTC- Skin, Product Safety-Skin and Hair Care).

Consulting Engagements:
2014-2023: Various via Gerson Lehrman Group. Litigation included.

2014-2016: Dermatologist Skin Care Brands- New Product Planning and Procurement- Skin Care/ Sun care; Materials, Formulations and regulatory compliance; Consumer Safety project management.

2012-2015: AlfaParf-Milano- Hair coloring; technology support

2011-2012; CRODA, Inc- Patent Infringement; raw materials.

2010-2011: Symrise GmbH. Skin Care ingredients (organic) and new materials.

2009-2010: Shaklee Products. Skin Care/ Sun care; Materials, Formulations and regulatory compliance; Consumer Safety project management: Litigation support.

2009- CRODA Inc., Patent Infringement; raw materials.

2009: International Flavors and Fragrances (IFF), Inc.- General advisement; strategic plan for new initiatives (food & beverage technologies)

2003: NuSkin Ltd. Dermatology based skin care; Sun Protection skin care, makeup globally; Nutritional Supplements. Litigation Support.

2002: E. I. DuPont, Technology repurposing; IP re-utilization.

Publications & Presentations

Patents

1. **US 4,887,675: Process for Dyeing Keratinous Fibers with Metal Catechol Derivatives** ; T. M. Schultz, J. Kijek, K. Brown, and L. J. Wolfram:

2. **US Patent Application: Dyeing Human Hair with N Substituted Dihydroxyindoles** ; T. M. Schultz, K. Brown, A. Mayer, B. P. Murphy, and M. I. Lim.

3. **US 4,984,553 : Process for Preparing DyeCompositions Containing 5,6Dihydroxyindoles and Products** ; L. J. Wolfram, K. Brown, B. P. Murphy, T. Schultz, and A. Mayer

4. **US 5,346,509: Use of 5,6Dihydroxyindole2 Carboxylic Acid as A Hair Dye** ; T. M. Schultz, L. J. Wolfram, K. Brown, and G. Prota.

5. **US 4,932,977 : Process for Dyeing Hair with AldehydeIndole Compositions** : T. M. Schultz.

6. **US 4,904,274 ; A Process for Coloring Hair with Catecholamine Derivatives** ; T. M. Schultz, L. J. Wolfram, K. Brown, and G. Prota.

7. **US 4,921,503 : The Use of 3Iminoarylindole2 Ones As Hair Dyes** ; J. S. Anderson and T. M. Schultz.

8. **US 5,049,381: Skin Tanning With Dihydroxindoles and Ammonium Salts** ; T. M. Schultz, A. Chan and L. J. Wolfram.

9. **US 5,037,640: PhotoChemical Tanning with Catalysts** ; A. Chan and T. M. Schultz.

10. **US 5,033,601: Skin Tanning Composition and Application** ; L. J. Wolfram, T. M. Schultz and A. Chan.

11. **US 5,032,138; Use of Chlorite as Oxidant in Hair Coloring** ; T. M. Schultz, K. Brown and A. Mayer.

12. **US 5,051,252: Novel Oxidant Compositions For Permanent Wave Neutralization** ; T. M. Schultz and E. Day.

13. **US 5,021,972: A Method Permanent Wave and Color Human Hair Concurrently**: T. M. Schultz and J. Patel..

14. **US 4,932,977 : Indole-Aldehyde Hair Dyes**; T. M. Schultz.

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