

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

VANTAGE SPECIALTY CHEMICALS, INC.,
Petitioner

v.

CARGILL, INC.,
Patent Owner

Case No. IPR2023-00589
Patent No. 11,248,245

**DECLARATION OF NANCY E. ADAMS Ed.D.
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 11,248,245**

I. INTRODUCTION

I, Nancy E. Adams Ed.D., do hereby declare as follows:

1. I have been retained as an independent expert witness on behalf of Vantage Specialty Chemicals, Inc. for proceedings before the United States Patent and Trademark Office (“PTO”) regarding the authenticity and public availability of certain prior-art references in relation to U.S. Patent No. 11,248,245.

2. I am being compensated for my work in this matter at my customary hourly rate, which is \$250/hour. I am also reimbursed for any reasonable expenses associated with my work on this matter. My compensation is not contingent on the results of my study, the substance of my opinions, or the outcome of this matter.

3. I understand that this Declaration accompanies a Petition for *Inter Partes* Review (“IPR”) involving U.S. Patent No. 11,248,245 (“the ’245 patent”) (**EX1001**), which resulted from U.S. Patent Application No. 14/578,075 (“the ’075 application”), filed on December 19, 2014. I understand that the ’075 application does not claim priority to any prior provisional or non-provisional patent applications (**EX1001, EX1002**), and therefore the priority date for the ’245 patent is December 19, 2014, which is the date I refer to throughout this declaration.

A. Qualifications and Professional Experience

4. My complete qualifications and professional experience are described in my curriculum vitae (**Appendix A**). The following is a brief summary of my relevant qualifications and professional experience.

5. I am the Assistant Dean of Foundational Sciences at Penn State College of Medicine and Librarian for Education and Instruction at Harrell Health Sciences Library. I have held this combined position since July of 2017. Prior to that, I held the position of Associate Director of the Harrell Health Sciences Library, which began in 2010. Prior to that, I held numerous Librarian positions at the University level, such as Harrisburg University of Science and Technology, The University of Maine, and Wayne State University. I have accumulated a total of 26 years of experience working in an academic library and medical library. I hold an Ed.D. in Adult Education from Pennsylvania State University and a Masters in Library and Information Science from Wayne State University.

6. I am an expert on library cataloging, classification, and searching. I have published contributed chapters to editions on this subject, *Curriculum Mapping: A Match Made for Librarian Skill* (2020), and *Making it better: library and student services collaboration at a new university* (2012). I have taught workshops on literature searching to a myriad of undergraduate students, graduate students, and advanced-degree professionals for decades. I have given

presentations, such as “Searching PubMed like an Expert: The Evolution, a PubMed Searching Discussion Forum.” I have served as the search specialist on a systematic review team in which my role was to formulate, execute, and document an exhaustive search of the literature answering a specific research question.

7. I am familiar with metadata schematic design and implementation. As a librarian, I routinely use the metadata associated with publications to answer reference questions or track down items that researchers rely on for their work. I have used online cataloging systems to create new catalog records for materials archived by libraries.

8. I am personally familiar with many online catalogs, databases, and search engines, including all of the particular catalogs, databases, and search engines that I relied upon in forming my opinions herein.

B. Scope of This Declaration

9. I have been asked to offer an opinion on the authenticity and public-availability date of the following documents:

- Cummings, Melanie et al., *A natural alternative*, SOAP, PERFUMERY, AND COSMETICS (SPC) ASIA (May 1, 1999) (**EX1004**, “*Cummings*”).
- Brown, James and Kleiman, Robert, *Trans Isomers in Cosmetics*, SOAP & COSMETICS (May 2001) (**EX1005**, “*Trans Isomers 1*” also in **EX1014**).

- Brown, James and Kleiman, Robert, *Trans Isomers in Cosmetics Part 2*, SOAP & COSMETICS (June 2001) (**EX1006**, “*Trans Isomers 2*” also in **EX1014**).
- Xu, Xuebing, *Engineering of enzymatic reactions and reactors for lipid modification and synthesis*, 105 EUR. J. LIPID SCI. TECH. 289 (2003) (**EX1008**, “Xu”).
- Xu, X., Guo. Z., Zhang, H., Vikbjerg, A.F., and Damstrup, M.L., *Chemical and enzymatic interesterification of lipids for use in food*, MODIFYING LIPIDS FOR USE IN FOOD, Ch. 11 (Woodhead Publishing 2006) (**EX1017**).
- Lopez-Hernandez, Arnoldo, Garcia, Hugo S., and Hill, Jr., Charles G., *Lipase-catalyzed Transesterification of Medium-chain Triacylglycerols and a Fully Hydrogenated Soybean Oil*, 70 J. FOOD SCI. 365 (2005) (**EX1018**).
- Sessa, David J., *Derivation of a Cocoa Butter Equivalent from Jojoba Transesterified Ester via a Differential Scanning Calorimetry Index*, 72 J. SCI. FOOD AGRIC. 295 (1996) (**EX1009**, “Sessa”).

C. Evidence Considered in Forming My Opinions

10. In preparing this Declaration, I have reviewed the documents I reference herein, and each of these is a type of material that experts in my field of

library cataloging and reference classification would reasonably rely upon when forming their opinions.

II. AUTHENTICITY AND PUBLIC AVAILABILITY OF PUBLICATIONS

A. EX1004: *Cummings*

11. In **EX1004**, page 1 shows the title and identifies the authors of the publication. Page 3 shows that *Cummings* was “Reprinted from **SPC Asia** May 1999.” **EX1004** shows that *Cummings* has a total of 3 pages, including 14 references.

12. **EX1004** is in a condition that does not create suspicion about its authenticity. Specifically, this copy is not missing any intermediate pages, the text on each page appears to flow seamlessly from one page to the next, and there are no visible alterations to the document. Accordingly, I see no reason to question the authenticity of this copy of *Cummings*.

13. My knowledge of library cataloging informs my opinion that *Cummings* was published in the May 1999 issue of Soap, Perfumery, and Cosmetics (SPC) Asia. For example, the catalog record for Cambridge University (**EX. A**) provides that Soap, Perfumery, and Cosmetics (SPC) Asia was a quarterly publication that began publishing in October/November 1996, and that it was published by Wilmington Publishing in Dartford, England. The University of Oxford online record further confirms through its catalog records (**EX. B**) that Soap,

Perfumery, and Cosmetics (SPC) Asia began publication in 1996, which is also confirmed by WorldCat, one of the world's largest library catalogs, at <<https://www.worldcat.org/title/60637274>>.

14. Moreover, the ISSN Portal (EX. C) confirms that Soap, Perfumery, and Cosmetics (SPC) Asia has the same ISSN (1365-4926) as indicated in the catalogue records for Cambridge University, the University of Oxford, and WorldCat, thus further confirming that this is the same publication that began in 1996.

15. Actual usage and the public availability of *Cummings* is further confirmed by other articles that pre-date the filing of the application leading '245 patent, which articles cite to *Cummings*. For example, Oliphant, Tiffany N. and Harper, Robert A., *Effect of Jojoba Esters on Skin Barrier Function, Skin Hydration, and Consumer Preference*, International Flora Technologies, Ltd. (2013) (EX. D), cites to *Cummings* and pre-dates the priority date of the '245 patent.

16. Moreover, I note that the applicant during prosecution of U.S. Patent Application No. 10/789,836 leading to U.S. Patent No. 7,201,919 submitted a copy of *Cummings* to the U.S. Patent Office on June 24, 2004, in which the applicant identified in entry number 50 as "Pamphlet – *A natural alternative*, Reprinted from SPC Asia, May 1999." (EX. J). Based on the description ("Pamphlet"), title ("*A natural alternative*"), and publication information

(“Reprinted from SPC Asia, May 1999”), this appears to refer to *Cummings*, thus further confirming that *Cummings* was available to the public prior to the filing of the application leading to the '245 patent (filed on December 19, 2014).

17. Based on the above, it is my professional opinion that *Cummings* would have become publicly accessible when it was published in May 1999 (EX1004), before December 19, 2014.

B. EX1005 & EX1006: *Trans* Isomers 1 and *Trans* Isomers 2

18. EX1005, page 1 shows the title and that it is from Soap & Cosmetics and that it is the online version of the article downloaded from Gale Business Insights: Global at <https://bi-gale-com.opl.idm.oclc.org/global/article/GALE%7CA75669667/e76471c06488f0e178118610c7d8ce14?u=oakland_main>. EX1005, page 4 shows that *Trans* Isomers 1 has nine references. EX1005, page 5 shows that the source citation of *Trans* Isomers is: “BROWN, JAMES, and ROBERT KLEIMAN. ‘Trans Isomers in Cosmetics.’ *Soap & Cosmetics* May 2001: 33.”

19. EX1006, page 1 shows the title and that it is from Soap & Cosmetics and that it is the online version of the article downloaded from Gale Business Insights: Global at <https://bi-gale-com.opl.idm.oclc.org/global/article/GALE%7CA76812413/35d7c144ae1a4ace77bfefa75cf020fa?u=oakland_main>. EX1006, page 5 shows that *Trans* Isomers 2 has

five references. **EX1005**, page 6 shows that the source citation of *Trans Isomers 2* is: “BROWN, JAMES, and ROBERT KLEIMAN. ‘Trans Isomers in Cosmetics Part 2.’ *Soap & Cosmetics* June 2001: 44.”

20. **EX1005** (*Trans Isomers 1*) and **EX1006** (*Trans Isomers 1*) are in a condition that does not create suspicion about its authenticity. Specifically, these copies are not missing any intermediate pages, the text on each page appears to flow seamlessly from one page to the next, and there are no visible alterations to the document. Accordingly, I see no reason to question the authenticity of these copies of *Trans Isomers 1* and 2.

21. My knowledge of library cataloging informs my opinion that *Trans Isomers 1* was published in the May 2001 issue of *Soap & Cosmetics*, and that *Trans Isomers 2* was published in the June 2001 issue of *Soap & Cosmetics*. For example, the catalog record for San Francisco Public Library (**EX. K**) provides that *Soap & Cosmetics* was a monthly publication that began publishing in January 1999, and that it was published by Cygnus Publishing in Melville, NY, which is also confirmed by WorldCat, one of the world’s largest library catalogs at <<https://www.worldcat.org/title/60621307>>.

22. I note that **EX1014** includes the same content as **EX1005** and **EX1006**. Also, **EX1014**, page 1 appears to be the cover of the June 2001 issue of *Soap & Cosmetics* featuring the title “Trans Isomers in Cosmetics.” **EX1014**, page 2 shows

the title of **EX1005** and identifies the authors. **EX1014**, page 4 identifies nine references matching those listed on page 4 of **EX1005**. **EX1014**, page 5 shows the title of **EX1006** and identifies the authors. **EX1014**, page 7 identifies nine references matching those listed on page 4 of **EX1005** and further states it is “Reprinted from **Soap & Cosmetics** May & June 2001 ©2004 Access Intelligence, 110 William Street, 11th Floor, New York, NY 10038.” This also confirms that *Trans* Isomers 1 and 2 were available to the public in *Soaps & Cosmetics* prior to the filing of the application leading to the ’245 patent (filed on December 19, 2014).

23. I also note that the ’245 patent states that: “Various additional background information on the structure, use, and of transesterification reactions using hydrogenated jojoba wax esters may be found in the articles by James Brown and Robert Kleiman ‘Trans Isomers in Cosmetics’, Parts 1 and 2, *Soap & Cosmetics*, May 2001, p. 33-36 and June 2001” (**EX1001** at column 12, lines 34-39).

24. Moreover, I note that the applicant during prosecution of the application leading to the ’245 patent submitted documents that match the titles (“Trans Isomers in Cosmetics” and “Trans Isomers in Cosmetics,” Part 2), publication (“*Soap & Cosmetics* [*sic*]”), and publication dates, (May and June 2001) of *Trans* Isomers 1 and 2 to the U.S. Patent Office (**EX1002** at 58); *see also* **EX1001** at 2 (“OTHER PUBLICATIONS”). This further confirms that *Trans* Isomers 1 and 2 were available to the public in *Soaps & Cosmetics* prior to the filing of the application leading to

the '245 patent (filed on December 19, 2014), as the applicant submitted *Trans* Isomers 1 and 2 as publicly available prior art to the '245 patent.

25. Based on the above, it is my professional opinion that *Trans* Isomers 1 would have become publicly accessible when it was published in May 2001 (**EX1005**) and that *Trans* Isomers 2 would have become publicly accessible when it was published in June 2001 (**EX1006**), before December 19, 2014.

C. EX1008: *Xu*

26. **EX1008** is a true and correct copy of Xu, Xuebing, *Engineering of enzymatic reactions and reactors for lipid modification and synthesis*, 105 EUR. J. LIPID SCI. TECH. 289 (2003) ("*Xu*"), that I obtained from the Wiley Online Library. I began my research by searching Wiley Online Library by the title of *Xu* for records, and a retrieved record led me to the full text of *Xu* in Wiley Online Library at <<https://onlinelibrary.wiley.com/doi/10.1002/ejlt.200390059>> that shows that *Xu* was published in the European Journal of Lipid Science and Technology, and that it was first published on June 5, 2003. I then followed the PDF link to download the full text of *Xu*. This published copy is presented as **EX1008** to the Petition for IPR in this proceeding.

27. I am familiar with the Wiley Online Library, which is an online library with digital copies of various printed publications, including journals, as maintained by John Wiley & Sons, Inc. I have experience using the Wiley Online

Library in my practice and find Wiley Online Library to be a reliable source of the publications contained in its catalog.

28. In **EX1008**, page 1 shows the title, author, journal volume, year of publication, and page numbers from the volume in which the article is presented. **EX1008** shows that *Xu* has a total of 16 pages, including 37 references.

29. **EX1008** is in a condition that does not create suspicion about its authenticity. Specifically, this copy is not missing any intermediate pages, the text on each page appears to flow seamlessly from one page to the next, and there are no visible alterations to the document. Accordingly, I see no reason to question the authenticity of this copy of *Xu*.

30. My knowledge of library cataloging informs my opinion that *Xu* was published in 2003 in the European Journal of Lipid Science and Technology. For example, the catalog records in the Penn State University Libraries catalog (**EX. E**) provide that the European Journal of Lipid Science and Technology was a monthly publication that was published in Weinheim, German by Wiley-VCH Verlag beginning in January 2000.

31. Actual usage and the public availability of *Xu* prior to the filing of the application leading to the '245 patent is further confirmed by its use in a Notice of References Cited by a U.S. Patent Office examiner, on December 22, 2008, and included as part of the file history for U.S. patent application no. 11/438,833, which

issued as U.S. Patent No. 10,119,098. **EX. F** (citing *Xu* and noting that it was “cited by examiner”).

32. Based on the above, it is my professional opinion that *Xu* would have become publicly accessible when it was published on June 5, 2003 (**EX1008**), before December 19, 2014.

D. EX1017: Xu, X., Guo. Z., Zhang, H., Vikbjerg, A.F., and Damstrup, M.L., *Chemical and enzymatic interesterification of lipids for use in food*, MODIFYING LIPIDS FOR USE IN FOOD, Ch. 11 (Woodhead Publishing 2006)

33. **EX1017** is a true and correct copy of Xu, X., Guo. Z., Zhang, H., Vikbjerg, A.F., and Damstrup, M.L., *Chemical and enzymatic interesterification of lipids for use in food*, MODIFYING LIPIDS FOR USE IN FOOD, Ch. 11 (Woodhead Publishing 2006), that was obtained from the Penn State University Libraries online library collection. **EX1017** appears as Chapter 11 in the book titled *Modifying lipids for use in food*, which was published by Woodhead in 2006. The published copy of Chapter 11 of *Modifying lipids for use in food* is presented as **EX1017** to the Petition for IPR in this proceeding. An excerpt from the table of contents of the electronic version of the book in which **EX1017** is published, containing the title, editor, ISBN number, and publisher of the book, showing that it was first published in 2006 by Woodhead Publishing Limited, is presented as **EX. G**.

34. **EX1017** has a total of 39 pages, including 7 reference pages.

35. **EX1017** is in a condition that does not create suspicion about its authenticity. Specifically, this copy is not missing any intermediate pages, the text on each page appears to flow seamlessly from one page to the next, and there are no visible alterations to the document. Accordingly, I see no reason to question the authenticity of this copy.

36. My knowledge of library cataloging informs my opinion that **EX1017** was published in 2006 by Woodhead Publishing Limited. For example, the WorldCat catalog records for *Modifying lipids for use in food* states that the book was published by Woodhead Publishing in 2006, and provides ISBN identifying numbers that match those contained in **EX. G**.

37. Based on the above, it is my professional opinion that **EX1017** would have become publicly accessible when it was published in 2006 (**EX1017**), before December 19, 2014.

E. EX1018: Lopez-Hernandez, Arnoldo, Garcia, Hugo S., and Hill, Jr., Charles G., *Lipase-catalyzed Transesterification of Medium-chain Triacylglycerols and a Fully Hydrogenated Soybean Oil*, 70 J. FOOD SCI. 365 (2005)

38. **EX1018** is a true and correct copy of Lopez-Hernandez, Arnoldo, Garcia, Hugo S., and Hill, Jr., Charles G., *Lipase-catalyzed Transesterification of Medium-chain Triacylglycerols and a Fully Hydrogenated Soybean Oil*, 70 J. FOOD SCI. 365 (2005), that I obtained from the Wiley Online Library. I began my research by searching Google Scholar by the title of **EX1018**

for records, and a retrieved record led me to the Wiley Online Library at <https://ift.onlinelibrary.wiley.com/doi/abs/10.1111/j.1365-2621.2005.tb11430.x> that shows that **EX1018** was published in the Journal of Food Science, and that it was first published on May 31, 2006. The citation for **EX1018** is J. Food Sci. v. 70, no. 6, pgs 365-372. I then followed the PDF link to download the full text of **EX1018**. This published copy is presented as **EX1018** to the Petition for IPR in this proceeding.

39. As noted above, I am familiar with the Wiley Online Library, which is an online library with digital copies of various printed publications, including journals, as maintained by John Wiley & Sons, Inc., and in my experience the Wiley Online Library is a reliable source of the publications contained in its catalog.

40. In **EX1018**, page 1 shows the title, authors, abstract, key words, and the date of web publication, which was July 13, 2005. **EX1018** shows that the publication has a total of 8 pages, including 15 references. The publication history included at the bottom of page 1 shows that it was originally submitted for peer review on November 24, 2004; a revised submission was submitted on January 27, 2005; it was accepted on April 4, 2005; and it was published in the Journal of Food Science's August 2005 issue.

41. **EX1018** is in a condition that does not create suspicion about its authenticity. Specifically, this copy is not missing any intermediate pages, the text on each page appears to flow seamlessly from one page to the next, and there are no visible alterations to the document. Accordingly, I see no reason to question the authenticity of this copy of **EX1018**.

42. Actual usage and the public availability of **EX1018** is further confirmed by other articles that pre-date the filing of the application leading '245 patent, which articles cite to it. For example, Wiley Online Library identifies 12 publications that cite to **EX1018** over the period of 2006-2013, all of which pre-date the priority date of the '245 patent. **EX. H.**

43. Based on the above, it is my professional opinion that **EX1018** would have become publicly accessible when it was published in 2005 (**EX1018**), before December 19, 2014.

F. EX1009: Sessa

44. **EX1009** is a true and correct copy of Sessa, David J., *Derivation of a Cocoa Butter Equivalent from Jojoba Transesterified Ester via a Differential Scanning Calorimetry Index*, 72 J. SCI. FOOD AGRIC. 295 (1996) ("Sessa"), that I obtained from the Wiley Online Library. I began my research by searching Google Scholar by the title of *Sessa* for records, and a retrieved record led me to the Wiley Online Library at <[https://onlinelibrary.wiley.com/doi/abs/10.1002/\(SICI\)1097-](https://onlinelibrary.wiley.com/doi/abs/10.1002/(SICI)1097-)

0010(199611)72:3%3C295::AID-JSFA657%3E3.0.CO;2-B> that shows that *Sessa* was published in the Journal of the Science of Food and Agriculture, and that it was first published in November 1996. The citation for *Sessa* is *J. Sci. Food Agric.* 1996, 72, 295-298. I then followed the PDF link to download the full text of *Sessa*. This published copy is presented as **EX1009** to the Petition for IPR in this proceeding.

45. In **EX1009**, page 1 shows the title, authors, abstract, key words, and the date of publication. Moreover, page 1 shows that the article was received on November 7, 1995, and accepted on June 3, 1996. **EX1009** shows that *Sessa* has a total of 4 pages, including 8 references.

46. As noted above, I am familiar with the Wiley Online Library, which is an online library with digital copies of various printed publications, including journals, as maintained by John Wiley & Sons, Inc., and in my experience the Wiley Online Library is a reliable source of the publications contained in its catalog.

47. **EX1009** is in a condition that does not create suspicion about its authenticity. Specifically, this copy is not missing any intermediate pages, the text on each page appears to flow seamlessly from one page to the next, and there are no visible alterations to the document. Accordingly, I see no reason to question the authenticity of this copy of *Sessa*.

48. My knowledge of library cataloging informs my opinion that *Sessa* was published in 1996 in the Journal of the Science and Food Agriculture. For example, the catalog records for the Penn State University Libraries (**EX. I**) provides that the Journal of the Science of Food and Agriculture was a monthly publication that was published in London, England by the Society of Chemical Industry beginning in January 1950.

49. I also note that the '245 patent states that: "Various additional background information on the structure, use, and of transesterification reactions using hydrogenated jojoba wax esters may be found . . . in . . . David J. Sessa, 'Derivation of a Cocoa Butter Equivalent from Jojoba Transesterified Ester via a Differential Scanning Calorimetry Index,' J. Sci. Food Agric., v. 72, p. 295-298 (1996)" (**EX1001** at column 12, lines 34-46).

50. Moreover, I note that the applicant during prosecution of the application leading to the '245 patent submitted a copy of *Sessa* to the U.S. Patent Office, in which the applicant identified that *Sessa* was published in "J. Sci. Food Agric., v. 79, p. 295-298" in 1996. **EX1002** at 323; *see also* **EX1001** at 3 ("OTHER PUBLICATIONS"). This further confirms that *Sessa* was available to the public in the Journal of the Science of Food and Agriculture publication years prior to the filing of the application leading to the '245 patent (filed on December 19, 2014), as the applicant submitted *Sessa* as publicly available prior art to the '245 patent.

51. Based on the above, it is my professional opinion that *Sessa* would have become publicly accessible when it was first published in November 1996 (**EX1009**), before December 19, 2014.

III. LIST OF DOCUMENTS CONSIDERED

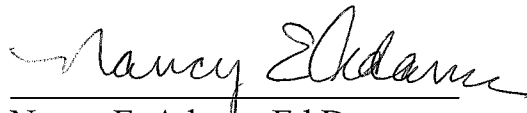
52. In addition to the documents attached to this Declaration, the documents I considered in formulating my opinions are as follows:

Exhibit No.	Description
1001	U.S. Patent No. 11,248,245
1002	File History of U.S. Patent No. 11,248,245
1004	Melanie Cummings et al., <i>A natural alternative</i> , SOAP, PERFUMERY, AND COSMETICS (SPC) ASIA (May 1, 1999) <i>available at</i> https://www.floratech.com/PDFs/Articles_MKT/ART15.pdf .
1005	James Brown & Robert Kleiman, <i>Trans Isomers in Cosmetics</i> , SOAP & COSMETICS at 33 (May 2001)
1006	James Brown & Robert Kleiman, <i>Trans Isomers in Cosmetics Part 2</i> , SOAP & COSMETICS at 44 (June 2001)
1008	Xuebing Xu, <i>Engineering of enzymatic reactions and reactors for lipid modification and synthesis</i> , 105 EUR. J. LIPID SCI TECH. 289 (2003)
1009	David J. Sessa, <i>Derivation of a Cocoa Butter Equivalent from Jojoba Transesterified Ester via a Differential Scanning Calorimetry Index</i> , 72 J. SCI. FOOD AGRI. 295 (1996)
1017	X. Xu et al., <i>Chemical and enzymatic interesterification of lipids for use in food</i> , in <i>Modifying lipids for use in food</i> 234 (Frank D. Gunstone, ed., 2006).
1018	Arnaldo Lopez-Hernandez et al., <i>Lipase-catalyzed Transesterification of Medium-chain Triacylglycerols and a Fully Hydrogenated Soybean Oil</i> , 70 J. FOOD SCI. C365 (Jul. 13, 2005).

IV. CONCLUSION

53. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, 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 Title 18 of the United States Code.

Respectfully submitted,


Nancy E. Adams, Ed.D.

Date: 2/23/23

APPENDIX A

Nancy E. Adams

Curriculum Vitae

59 Hellam Dr.
Mechanicsburg, PA 17055
717-315-8302
nancyeadams@hotmail.com

Education

EdD, Penn State Harrisburg, Harrisburg, PA, 2016.
Major: Adult Education
Dissertation Title: Dialog about Psychosocial Issues in Problem-Based Learning Sessions in Medical Education

MLIS, Wayne State University, Detroit, MI, 1996.
Major: Library and Information Science

BS, Magna cum laude, Harding University, Searcy, AR, 1990.
Major: Chemistry

Professional Positions

Academic

Assistant Dean, Foundational Sciences, MD Program, Penn State College of Medicine and Librarian for Education and Instruction, Harrell Health Sciences Library, Penn State College of Medicine. (July 2017-Present).

Associate Director, Harrell Health Sciences Library, Penn State College of Medicine. (July 2010-June 2017).

University Librarian and Director of Student Services, Harrisburg University of Science and Technology. (December 1, 2009 - June 25, 2010).

University Librarian, Harrisburg University of Science and Technology. (July 1, 2008 - December 1, 2009).

Reference and Instruction Librarian, Harrisburg Area Community College. (September 2006 - June 2008).

Librarian II, University of Maine. (September 1998 - December 2000).
Reference and instruction in patent and trademark information, science, and engineering.

Librarian I, Wayne State University Shiffman Medical Library. (October 1996 - August 1998).
Lead instructor of grant-funded program that trained high school vocational healthcare students in the use of health sciences information resources; reference and instruction services at an academic medical center.

Science Teacher, Edsel Ford High School, Dearborn, MI. (August 1993 - June 1994).
Taught high school physical science, chemistry, and life science.

Science Teacher, Harding Academy, Memphis, TN. (August 1992 - June 1993).
Taught high school physics and physical science.

Science Instructor, Harding University. (August 1991 - May 1992).
Taught chemistry and physical science.

Science Instructor, Crowley's Ridge College, Paragould, AR. (January 1991 - August 1991).
Taught college botany, chemistry, and biology.

Awards and Honors

Exceptional Teacher mention, Penn State College of Medicine Office for Respectful Learning Environment. (December 2020 - Present).

Penn State University Libraries Teaching Award, Penn State University Libraries. (May 24, 2016 - April 30, 2017).

Top 20 Library Instruction Article, Library Instruction Round Table, American Library Association. (January 2016 - December 2016).

Innovation in Instruction Award, Association of College and Research Libraries. (1998).

Outstanding Academic Staff Contributor Award, Wayne State University, Academic Staff Professional Development Committee. (1998).

TEACHING ACTIVITIES, SELECTED

Co-Director and Instructor of Record of Credit-Bearing Course

HMN 797, Foundations of Health Humanities, Fall 2021, MD Program, Penn State College of Medicine

Lead Faculty Member, Evidence-Based Medicine Unit of MED 797b, Science of Health Systems

Small Group Facilitator in Required Courses in the MD Curriculum

HMN 713, Medical Humanities

HMN 715, Science of Mind and Body

TMS 721 Transition to Medical School

HMN 723 Communication

MED 797b Science of Health Systems

Interprofessional education sessions in Science of Health Systems and Foundations of Patient-Centered Care

Course-Integrated Information Literacy Instruction

Evidence-Based Medicine OSCE Assessor, Family and Community Medicine Residency

Scientific Principles of Medicine Course, Searching PubMed like an Expert Module

RESEARCH

Intellectual Contributions

Articles Published in Refereed Journals

Moniz, T., Golafshani, M., Gaspar, C., Adams, N. E. (Co-Author, 10%), Haidet, P., Sukhera, J., Volpe, R., de Boer, C., & Lingard, L. (2021). The Prism Model: Advancing a theory of practice

- for arts and humanities in medical education. *Perspectives in Medical Education*, 8 pages. DOI: <https://doi.org/10.1007/s40037-021-00661-0>
- Moniz, T., Golafshani, M., Gaspar, C., Adams, N. E. (Co-Author, 10%), Haidet, P., Sukhera, J., Volpe, R., de Boer, C., & Lingard, L. (2021). How are the arts and humanities used in medical education?: Results of a scoping review of published literature. *Academic Medicine*, 96(8), 1213-1222. DOI: 10.1097/ACM.0000000000004118
- Moniz, T., Golafshani, M., Gaspar, C., Adams, N. E. (Co-Author, 10%), Haidet, P., Sukhera, J., Volpe, R., de Boer, C., & Lingard, L. (2021). The Prism Model for integrating arts and humanities into medical education. *Academic Medicine*, 96(8), 1225. DOI: 10.1097/ACM.0000000000003949
- Duca, N., Adams, N. E. (Co-Author, 40%), Glod, S., & Haidet, P. (2020). Barriers to Teaching Clinical Reasoning in the Medicine Clerkship: A Qualitative Study of Medicine Clerkship Students. *Medical Science Educator*, 30, 1495–1502. DOI: <https://doi.org/10.1007/s40670-020-01069-x>
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- Adams, N. E. (2014). A Comparison of Evidence-Based Practice and the ACRL Information Literacy Standards: Implications for Information Literacy Practice. *College and Research Libraries*, 75(2), 232-248.
- Tomasko, J. M., Adams, N. E. (Secondary Author, 20%), Garritano, F. G., Santos, M. C., & Dillon, P. C. (2014). Collaborating to Increase Access to Clinical and Educational Resources for Surgery: A Case Study. *Journal of Surgical Education*, 71(1), 32-5.

Adams, N. E. (Co-Author, 50%), & Young, J. B. (2010). Users learning from users: building a learning commons from the ground up at a new university. *College & Undergraduate Libraries*, 17(2 & 3), 149-159.

Parts of Books

Kovar-Gough, I., & Adams, N. E. (Co-Author, 50%) (2020). Curriculum Mapping: A Match Made for Librarian Skills. In Lindsay Alcock and Kelly Thormodson (Eds.), *The Engaged Health Sciences Library Liaison* Chicago, IL: Medical Library Association.

Adams, N. E. (Primary Author, 95%), & Olivetti, J. K. (2012). Making it better: library and student services collaboration at a new university. In Lisa Janicke Hinchliffe and Melissa Wong (Eds.), *Environments for Student Growth and Development: Libraries and Student Affairs in Collaboration* (pp. 57-72). Chicago, IL: Association of College and Research Libraries.

Instructional Material, Instructor's Manual

Felix, T., Richard, D., Faber, F. S., Zimmermann, J., & Adams, N. E. (Co-Author, 5%) (2015). CoffeeTalks: An Innovative Approach to Teaching Clinical Reasoning and Information Mastery to Medical Students. *MedEdPortal*. Association of American Medical Colleges. DOI: 10.15766/mep_2374-8265.10004

Journal Article, In House

Robinson, C. K., & Adams, N. E. (Co-Author, 50%) (2011). Understanding the impact of health information and evidence based practice. *Interview*, 5(24), 1.

Magazine/Trade Publication

Chappell-Williams, L., Adams, N. E. (Co-Author), & Wang, J. (2018). "Creating an inclusive medical education curriculum." *INSIGHT Into Diversity*. (December 2018), (pp. 2).

Technical Report

Bivens-Tatum, W., & Adams, N. E. (Co-Author, 10%), et al. (2017). ACRL Environmental Scan 2017.

White Paper released by National Professional Organization

Howley, L., Gaufberg, E., King, B., et al. & Adams, N. E. (2020). *The Fundamental Role of the Arts and Humanities in Medical Education*. (pp. 3). Washington, DC: Association of American Medical Colleges.

Research Reports to Sponsor

Moniz, T., Golafshani, M., Haidet, P., Lingard, L., Adams, N. E., Apramian, T., Arntfeld, S., de Boer, C., Dell, E., Gaspar, C., Sukhera, J., Volpe, R., *Final Report: Scoping review on the use of arts and humanities in the education of physician and interprofessional learners across the developmental spectrum*. 169 pp. Final Report, Association of American Medical Colleges. (January 15, 2020).

Presentations Given, Selected

- Adams, N. E., & Cirelli, M. C. (June 14, 2019). "Searching PubMed like an Expert: The Evolution," PubMed Searching Discussion Forum, ACRL Health Sciences Interest Group, Virtual, 250 in attendance, peer-reviewed/refereed. International.
- Glendinning, D. (Rutgers Robert Wood Johnson Medical School), Willett, L. (Rutgers Robert Wood Johnson Medical School), Moser, E. (Penn State College of Medicine), Kim, S. (Rutgers Robert Wood Johnson Medical School), & Adams, N. E. (June 2018). "Moser, E., Kim, S., Adams, N. Discriminant Validation of new test of Evidence-based Medicine." Annual Meeting, IAMSE, Las Vegas, NV, peer-reviewed/refereed. International.
- Adams, N. E. (Co-Author), Collins, H., Kovar-Gough, I., Lorbeer, E., Nicholson, J., Spak, J., Brennan, E., Ogawa, R., Rambo, N., Thormodson, K., & von Isenburg, M. (May 20, 2018). "Identifying the Role of the Medical Librarian in Clinical Competency Entrustment," Annual Meeting, Medical Library Association, Atlanta, GA, peer-reviewed/refereed. National.
- Collins, H. (University of Kansas Medical Center), Adams, N. E., & Brennan, E. (Medical University of South Carolina (MUSC) Library, Medical University of South Carolina). (November 7, 2017). "Competency-Based Medical Education & the Role of Medical Librarians: Trends, Challenges, and Opportunities," Association of American Medical Colleges Annual Meeting, Boston, MA, peer-reviewed/refereed. National.
- Adams, N. E., & (AAHSL Task Force Evaluating AAMC Core EPAs). (May 29, 2017). "AAHSL Task Force on Evaluating AAMC Core EPAs," Annual Conference, Medical Library Association, Seattle, WA, peer-reviewed/refereed. National.
- Adams, N. E., Gaffney, M. A., & Lynn, V. A. (March 24, 2017). "What Counts as Knowledge?: Concrete Examples of an Abstract Concept from the ACRL Framework for Information Literacy," Biannual Conference, Association of College and Research Libraries, Baltimore, MD, peer-reviewed/refereed. National.
- Adams, N. E., & Members (AAHSL Task Force on Evaluating AAMC Core EPAs). (March 23, 2017). "Can I Trust You?: Librarians' Involvement in Competency-Based Medical Education," Biannual Conference, Association of College and Research Libraries, Baltimore, MD, peer-reviewed/refereed. National.
- Collins, H. (University of Kansas Medical Center), Adams, N. E., & Brennan, E. (Medical University of South Carolina (MUSC) Library, Medical University of South Carolina). (November 13, 2016). "AAHSL Task Force Investigating Librarian Involvement in AAMC Core EPA," Association of American Medical Colleges Annual Meeting, Seattle, WA, peer-reviewed/refereed. National.
- Adams, N. E. (April 8, 2016). "Dialog about Psychosocial Topics in Problem-Based Learning Sessions," Annual Meeting, North East Group on Educational Affairs, Providence, RI, 40 in attendance, peer-reviewed/refereed. Regional.
- Adams, N. E. (May 11, 2015). "Design and implementation of a performance-based assessment of information management and critical appraisal skills for medical students," Pennsylvania Regional Innovations In Medical Education Meeting, Thomas Jefferson School of Medicine, Philadelphia, PA, 25 in attendance, Invited. Local.
- Adams, N. E. (Panel Member), Lonn, S. (University of Michigan), & Fransen, J. (University of Minnesota). (March 2015). "Learning Analytics and Privacy: Multi-Institutional Perspectives on Collecting and Using Library Data," Biannual Conference, Association of College and Research Libraries, Portland, OR, peer-reviewed/refereed. National.

Adams, N. E. (Author and Presenter, Penn State Hershey George T. Harrell Health Sciences Library). (May 18, 2014). "Theory-based Techniques for Active Learning in the Evidence-Based Medicine Classroom," Annual Conference, Medical Library Association, Chicago, IL, peer-reviewed/refereed.

Adams, N. E. (Co-Presenter, Penn State Hershey George T. Harrell Health Sciences Library), Adelman, A. (Penn State Hershey), & Zimmerman, J. (Penn State Hershey). (May 4, 2013). "Flipping The Classroom – A Method to Transform Your Lectures," 46th STFM Annual Spring Conference, Society of Teachers of Family Medicine, Baltimore, MD, 80 in attendance, peer-reviewed/refereed. National.

Tomasko, J. M. (Penn State Hershey), Adams, N. E. (Co-Author), Foley, T. T. (Penn State Hershey), Goyal, N. (Penn State Hershey), Garritano, F. (Penn State Hershey), Santos, M. C. (Penn State Hershey), Wilson, M. Z. (Penn State Hershey), Han, D. (Penn State Hershey), & Dillon, P. (Penn State Hershey). (March 22, 2012). "Designing a Single Portal eLibrary Site to Facilitate Surgical Education," Annual Conference, Association for Surgical Education, San Diego, CA. National.

Contracts, Grants, and Sponsored Research

Grants, Selected

Adams, N. E. (Co-Investigator), Volpe, R. (Principal Investigator), Wolpaw, D. R. (Co-Investigator), Grant, 10% credit, "Investigating professional identity formation across professions to inform medical education: A systematic review," Arnold P. Gold Foundation [MP], Nonprofit Foundations. Total requested: \$4,923.00, Total Anticipated: \$5000, Amount Funded (Total or To Date, as applicable): \$5000. (Submitted: July 12, 2016, date funding awarded: October 24, 2016, total start and end of funding: September 1, 2016 - August 31, 2017).

Adams, N. E. (Co-Investigator), Green, M. J. (Co-Investigator), Shapiro, D. E. (Co-Investigator), Stuckey, H. L. (Co-Investigator), Wolpaw, D. R. (Co-Investigator), Grant, 10% credit, "Developing a Conceptual Model to Guide Implementation and Study of the Arts in Medical Education," Arnold P. Gold Foundation [MP], Nonprofit Foundations. Total requested: \$6,000.00, Total Anticipated: \$6000, Amount Funded (Total or To Date, as applicable): \$5000. (Submitted: June 10, 2013, date funding awarded: August 21, 2013, total start and end of funding: August 30, 2013 - February 28, 2015.)

Adams, N. E. (Co-Principal Investigator), Glendinning, D. (Co-Principal Investigator), O'Rourke, K. (Co-Investigator), Moser, E. (Co-Investigator), Grant, "Development and validation of a new tool to assess knowledge and skills in Evidence-based Practice.," Northeast Group on Educational Affairs, Associations, Institutes, Societies and Voluntary Health Agencies. Total requested: \$4,808.00, Amount Funded (Total or To Date, as applicable): \$4808. (Submitted: September 30, 2014, date funding awarded: December 8, 2014.)

Adams, N. E. (Co-Investigator), Faber, F. Samuel (Co-Investigator), Felix, T. M. (Principal Investigator), Richard, D. C. (Co-Investigator), Grant, 25% credit, "Enhancing Teaching Methods and Evaluation of EBM and Clinical Reasoning: Faculty Development through Educational and Collaborative Efforts at McMaster's University, University," Woodward Endowment, Nonprofit Foundations. Total requested: \$9,820.00, Total Anticipated: \$9812, Amount Funded (Total or To Date, as applicable): \$9812. (Submitted: April 3, 2012, date funding awarded: April 3, 2012, total start and end of funding: April 1, 2012 - March 31, 2013).

Adams, N. E. (Principal Investigator), Grant, 100% credit, "Attendance at Supporting Clinical Care: An Institute in Evidence-Based Practice for Medical Librarians," Woodward Endowment, Nonprofit Foundations. Total requested: \$1,420.00, Total Anticipated: \$1420, Amount Funded (Total or To Date, as applicable): \$1420. (Submitted: May 16, 2011, date funding awarded: May 16, 2011, total start and end of funding: May 15, 2011 - May 14, 2012.)

Adams, N. E. (Principal Investigator), Grant, "Library Services and Technology Act Award," Office of Commonwealth Libraries, PA, State. Total requested: \$19,400.00, Amount Funded (Total or To Date, as applicable): \$19000. (Submitted: September 11, 2009, total start and end of funding: May 1, 2010 - May 31, 2011.)

Robinson, C. K. (Co-Principal Investigator), Adams, N. E. (Co-Principal Investigator), Brennan, D. P. (Co-Principal Investigator), Grant, 33% credit, "Improved Access to Biomedical Information Resources via E-book Readers," National Networks of Libraries of Medicine, Middle Atlantic Region, Federal. Total requested: \$7,128.00, Amount Funded (Total or To Date, as applicable): \$7128. (Submitted: August 2010, total start and end of funding: September 15, 2010 - March 30, 2011.)

SERVICE, SELECTED

Committee Work at Penn State College of Medicine and Penn State University Libraries

Curriculum Working Group, Diversity and Inclusion Task Force, Co-Leader (June-July 2020).

Propose strategic priorities for PSCOM curricula to address anti-bias and structural and system racism.

Physician Assistant Curriculum Committee (PAMPEC) (2020-present)

Oversees and advises regarding curriculum in the Penn State College of Medicine Physician Assistant Program.

Student Educator Award Selection Committee, Woodward Endowment for Medical Education, Committee Member. (January 2019 - Present).

Review portfolios of student educators who are nominated for awards at College of Medicine; select final awardees with committee.

Curriculum Committee for Undergraduate Medical Education. (2017-present).

Decision-making body for curriculum offerings and policies of the MD program of the Penn State College of Medicine.

College of Medicine Admissions Team, Member. (October 2015 - 2017).

Select candidates for admission to College of Medicine.

Medical School Applicant Interviewer. (September 2014 - present).

Reviewed application materials and submitted written evaluations for these students.

Liaison Committee for Medical Education Accreditation SubGroup, Penn State college of Medicine, Committee Member. (December 2015 - July 2017).

Collect data and write narrative for 2017 institutional self-study for the medical program of study. Lead two small subgroups for Standards 6 & 7.

Surgery Education Committee, Member. (June 2011 - July 2017).

Meet monthly to discuss issues with and improvements to surgery education at College

of Medicine, specifically clerkships for medical students and surgical residency program.

AD-14 Committee, AD-14 Committee for Review of Dean of Libraries, Penn State University Provost's Office, Member. (October 2015 - January 2016).

Interviewed individuals and compiled survey data from faculty, staff, and students relating to performance of Dean of University Libraries. Synthesized information into a report that was presented to the Provost.

Evidence-Based Medicine (EBM) Curriculum Task Force, Member. (July 2015 - October 2015).

To review EBM curriculum and recommend changes to how this thread is taught in the Science of Health Systems course (required of all medical students) and other longitudinal changes integrated throughout the curriculum. Currently the only librarian on the task force; all other members are physicians and basic scientists.

Participation in Development/Fundraising Activities

Penn State College of Medicine Development, Presenter. (May 2019 - Present).
Meet with donors for the College of Medicine and present a session in which they experience a problem-based learning session as "learners."

Faculty Development

Instructor, Health Systems Science Academy. (2018-present)

Teach a session on adult education theory, including how to write effective learning objectives. This session prepared attendees to be more effective in providing training, which often is part of health care systems improvement projects.

Facilitator for Focused Teaching Project, Junior Faculty Development Program, Facilitator. (February 15, 2019).

Facilitate small groups of participants as they present a mini-teaching session to others in group; provide constructive feedback to each participant.

Junior Faculty Development Program, Mentor. (December 1, 2014 - May 2015).

Asked to serve as mentor for junior faculty in Penn State College of Medicine in formal Junior Faculty Development Program.

Search Committee for Harrell Health Sciences Library Associate Dean, Member. (July 2018 - November 2018).

Faculty Governance

Library Faculty Organization, Chairperson, Elected. (May 1, 2013 - April 29, 2014).

Heard concerns of library faculty (130 throughout Commonwealth) and worked to resolve them through means available to LFO. Oversaw several standing committees of LFO and communicated with library faculty throughout system. All told, a three-year commitment including chair-elect and immediate past chair.

Service to the Disciplines and to the Profession

External evaluator for teaching award

Reviewer, Case Western Reserve Scholarship in Teaching Award, Case Western Reserve University School of Medicine, External Reviewer, Regional. Cleveland, Ohio. (January 2019 - Present).

Review applicant descriptions of teaching projects to evaluate their scholarly approach to

the project according to stated criteria. I have done this in 2019 and 2020.

Organizing Conferences and Service on Conference Committees

Medical Library Association, Garfield Research Fellowship Jury, Chairperson, International. (June 1, 2016 - May 31, 2017).
Select recipients of this competitive fellowship award.

Adult Education Research Conference, Co-Chairperson, National. Hershey, PA USA. (January 2013 - June 4, 2014).
Co-chaired and planned this one-day pre-conference with Dr. Elizabeth Tisdell of Penn State Harrisburg.

Association of College and Research Libraries, Professional Development Coordinating Committee, Virtual Institutes Committee, Member, National. (Virtual). (January 2010 - July 2012).
Create, implement, and evaluate ACRL virtual institute for 2012. Develop theme(s), identify co-sponsor(s), draft call for participation and selection criteria.

Participation in or Service to Professional and Learned Societies

AAHSL Task Force on Competency-Based Medical Education, American Association of Health Sciences Libraries, Member, National. (May 30, 2016 - November 2018).

- Identify AAHSL libraries that are participating to a significant degree in incorporating Core EPAs in the medical education curriculum, through design, development, teaching, evaluation, and/or similar engagement.

- Develop a methodology to characterize the nature and depth of the participation.

- Map and cross-reference existing ACGME, AAMC, LCME, and other evidence-based medicine competencies as identified by the Task Force. Identify gaps in EBM competencies.

- Compose a white paper or similar work for publication on the state of the art of librarians' roles and involvement in all phases of competency-based medical education. Include recommendations for additional work that is needed (e.g., developing standard definitions of EBM concepts, translating EBM concepts into teachable components, evaluation of the effectiveness of EBM curriculum.)

Association for College and Research Libraries Research Planning and Review Committee, Vice Chair, National. (July 1, 2017 - August 30, 2017).

Responsible for creating and updating a biennial environmental scan for the association that encompasses trends in academic librarianship, higher education, and the broader environment, e.g., economic, demographic, political, for release at the ACRL conference. Identifies the "ACRL Top 10 Trends" for release every two years in non-ACRL conference years.

[SPC Asia](#)

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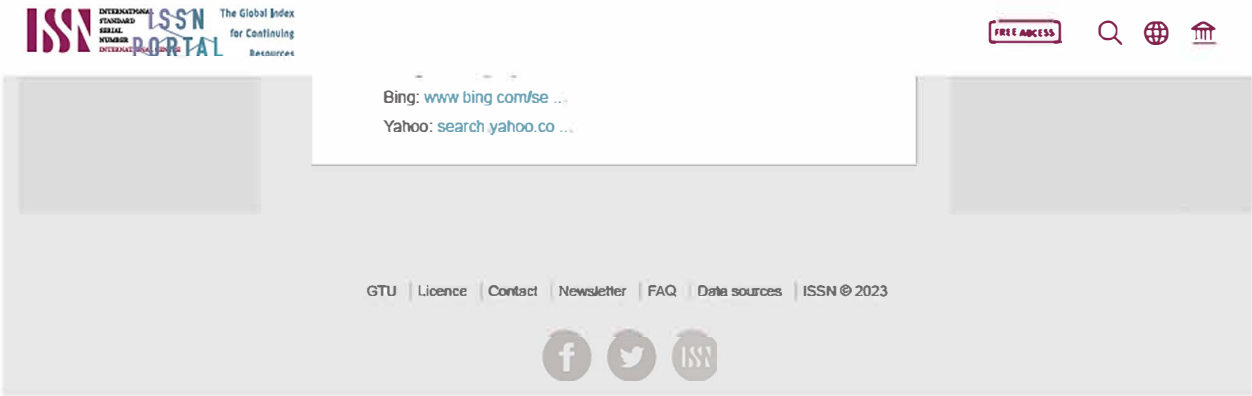
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Title

Effect of Jojoba Esters on Skin Barrier Function, Skin Hydration, and Consumer Preference

Author

Tiffany N. Oliphant, M.S., C.C.R.C. and Robert A. Harper, Ph.D., Consultant

Abstract

Previous literature shows that jojoba oil and jojoba oil derivatives have multiple skin benefits associated with anti-inflammation, barrier function, and skin hydration. The current research explores the action of Jojoba Esters with different melting points on the improvement of barrier function after sodium lauryl sulfate (SLS) insult, reduction of barrier disruption when applied prior to SLS insult, and on skin hydration as compared to known petrolatum-alternatives. In addition, a consumer preference study was carried out comparing Jojoba Esters with a known marketed petrolatum alternative ingredient. The data show that Jojoba Esters have the capability of reducing damage to the skin barrier, as measured by TEWL, in a dose dependent manner, and can accelerate the recovery of the SLS damaged skin barrier. The data also show that the Jojoba Esters, when added to a vehicle formula, produced statistically significant increases in skin hydration when compared to the vehicle and to the marketed petrolatum-alternative ingredients formulated in the same vehicle. Moreover, the formula containing the Jojoba Esters produced levels of skin hydration that were not statistically significantly different from 10% petrolatum formulated into the same vehicle. Additionally, the consumer preference study showed that the subjects preferred the Jojoba Esters formula over the petrolatum alternative ingredient formula with regard to skin moistness, suppleness, and smoothness/softness as well as stickiness and residue of the formulas immediately after application.

Introduction

There is a substantial body of evidence supporting the characterization of atopic dermatitis by epidermal barrier dysfunction,¹⁻³ leading to an increase in transepidermal water loss (TEWL).⁴⁻⁶ In atopic dermatitis, a role for stratum corneum lipids in the etiology of the disease has evolved, with special interest in the ceramides.⁷⁻¹⁰ This strong relationship with ceramides and atopic dermatitis has led to the inclusion of ceramides in topical formulations for the treatment of this skin condition.¹¹

In addition to ceramides, a number of ingredients over the years have been formulated into topical products to help restore skin barrier integrity. These have included petrolatum, silicones, glycerin, mineral oil and lipids.¹² Another class of ingredients with properties similar to petrolatum, but made from botanical sources, are the Jojoba Esters. These are a family of unique wax esters, with different melting points and degrees of firmness. Jojoba Esters are derived from the interesterification of jojoba oil with fully hydrogenated jojoba oil,¹³ yielding a mixture of wax ester, C36 –C46, which are “*trans*” free esters in nature.¹⁴ Jojoba Esters have been used in a variety of personal care product categories for their ability to provide emolliency and oxidative stability,¹⁴⁻¹⁵ including but not limited to, moisturizers, hair care, and color cosmetics¹⁵ such as lipsticks.¹⁶ In the present paper, we demonstrate the ability of Jojoba Esters to increase skin barrier recovery and reduce skin barrier disruption due to sodium lauryl sulfate (SLS), increase skin hydration similar to petrolatum, and enhance consumer preference.

Jojoba Esters with three different melting points were studied in five separate vehicle-controlled *in vivo* studies: (1) an initial barrier function study in which the skin was treated with Jojoba Esters before SLS exposure followed by (2) a dose response study to determine the minimum concentration of Jojoba Esters to produce the maximum barrier protection from SLS,

(3) a barrier recovery study in which the skin was treated with Jojoba Esters following SLS exposure, (4) a skin hydration study in which Jojoba Esters were compared to other petrolatum-alternatives over four hours, and (5) a consumer preference study in which a consumer survey was used to compare Jojoba Esters to a known petrolatum-alternative ingredient.

Materials and Methods

Subjects – All studies were conducted in the Clinical Testing Laboratory at Floratech, Chandler, Arizona. Institutional Review Board approval and a written informed consent from each subject were obtained before any protocol-related procedures were undertaken. All study participants were healthy males and females with normal appearing inner forearm skin, outer leg skin, or hands (as applicable). Upon arriving at the testing facility for each study, subjects acclimated for 30 minutes in a controlled environment with a temperature of 20-22° C and a relative humidity of less than 50%. All studies were carried out in a double-blind, vehicle-controlled, randomized fashion. A total of 71 subjects (55 females and 16 males) ranging in age from 25 to 65 years participated in the studies. All subjects underwent a one to two day “washout” where a commercial soap, supplied to them by the testing lab, was used to wash their forearms, legs, or hands (as applicable). The subjects were instructed not to use any topical products on the test sites during the washout period and the duration of the study.

Test Materials – The vehicle formulation for all studies included the following ingredients (w/w): Water (qs), Glyceryl Stearate (and) PEG-100 Stearate (4.00%), Cetyl Alcohol (3.00%), Phenoxyethanol (and) Methylparaben (and) Ethylparaben (and) Butylparaben (and) Propylparaben (0.80%), Xanthan Gum (0.20%) and Disodium EDTA (0.03%). The test articles included either various Jojoba Esters^a with different melting points, a petrolatum alternative

^a Jojoba Esters were obtained from International Flora Technologies, Ltd. (Chandler, AZ, USA).

[Castor Isostearate Succinate (and) Hydrogenated Castor Oil^b, Canola Oil (and) Zea Mays (Corn) Starch (and) Silica^c, or *Butyrospermum parkii* (Shea Butter)], or Petrolatum,^d in addition to the vehicle formula. Jojoba Esters (*i.e.* INCI name) used in this study were Floraesters[®] 20, mp=45°C; Floraesters 30, mp=50°C; and Floraesters 60, mp=60°C.

Evaluation of Barrier Function (Pre-SLS Treatment) – For Study 1, a total of six, one inch by one inch, test sites were assigned as follows: the vehicle lotion, 2% Floraesters 20, Floraesters 30, or Floraesters 60 in the vehicle lotion, 5% petrolatum in the vehicle lotion (positive control), and untreated skin (negative control). Each test site was demarcated on the inner aspects of the lower arms, located between one inch below the elbow and one inch above the wrist.

Following test site demarcation, baseline TEWL readings (in duplicate) were taken at each site using the Tewameter TM 300 (Courage + Khazaka, Köln, Germany) followed by one application of each test article. At time zero, 20 µl of each test article (vehicle, 2% Floraesters 20, 2% Floraesters 30, 2% Floraesters 60, or 5% petrolatum) was applied to the appropriate skin test site using a one milliliter syringe and spread evenly over the site with a finger cot. For the untreated site, a finger cot was rubbed across the site to mimic the test article application process. After 15 minutes, a 19mm Hill Top Chamber[®] (Hill Top Research Incorporated, St. Petersburg, FL, USA) containing 60 µl of a 0.3% solution (w/w) of SLS^e was placed in the center of each test site. Each chamber was then taped with First Aid Secure- Comfort[®] Soft Tape (Johnson & Johnson Corporation, New Brunswick, NJ) and then overlaid with Coban[®] Self-Adhering Wrap (3M Company, St. Paul, MN). Subjects were then permitted to leave the testing facility and

^b Zenolatium[®] (Zenitech LLC Corporation, Dacula, GA, USA)

^c Vegetatum[®] (Natunola Health Inc., Winchester, Ontario, Canada)

^d Petrolatum was obtained from International Group, Inc (Toronto, ON, Canada).

^e Sodium lauryl sulfate was obtained from Lubrizol Corporation (Cleveland, OH, USA).

instructed to leave the chambers undisturbed for approximately 12 hours without getting them wet.

Subjects returned to the testing facility, Day 2, and the Hill Top Chambers were removed. The subjects equilibrated for approximately 30 minutes in an environment with a temperature of 21.4-22.2°C and a relative humidity between 40-50% followed by final TEWL readings.

Study 2 was a dose response study conducted in the same manner as Study 1. Five concentrations of Floraesters 60 were evaluated (2%, 1.5%, 1%, 0.5%, and 0.2%). A total of 8 test sites were demarcated: the vehicle lotion, Floraesters 60 at five concentrations in the vehicle lotion, 2% petrolatum in the vehicle lotion (positive control), and untreated skin (negative control).

Evaluation of Barrier Recovery (Post-SLS Treatment) – For Study 3, six approximately one inch by one inch squares were demarcated on the inner aspects of the lower arms of each subject, between one inch below the elbow and one inch above the wrist. These included the vehicle lotion, 2% Floraesters 20, 2% Floraesters 30, or 2% Floraesters 60 in the vehicle lotion, 5% petrolatum in the vehicle lotion (positive control), and untreated skin (negative control).

Following test site demarcation, baseline TEWL measurements were taken at each test site in duplicate using the Tewameter, followed by disruption of the barrier using a solution of 0.3% SLS applied under occlusion in Hill Top Chambers. Subjects were then permitted to leave the testing facility. Approximately 18 hours after SLS application the subjects returned to the testing facility, Day 2, where the Hill Top Chambers were removed. Following a 30 minute acclimation period under controlled environmental conditions, TEWL measurements were taken at each site. Test articles were then applied to each site hourly for a total of three applications. TEWL measurements were repeated one hour after each test article application.

Evaluation of Skin Hydration – For Study 4, the skin hydration study, all subjects had a Corneometer reading of 35 or less on the outer aspect of each lower leg in order to be enrolled into the study.

Once enrolled, four approximately four centimeter by four centimeter squares were demarcated on the outer aspect of each lower leg of each subject, approximately three inches below the knee to approximately three inches above the ankle. Eight test sites were demarcated: six experimental, one negative control (distilled water), and one positive control (10.0% petrolatum in the vehicle). The sites were rotated from the right to left lower outside leg among the subjects as well as from top to bottom of the leg in order to remove any position bias. Baseline Corneometer readings (in triplicate) were taken at each site. Following baseline measurements, one 40 µl application of each test article was made to the designated test site by the clinical staff and spread over the site with a finger cot. Skin hydration measurements were then taken every hour for four hours.

Evaluation of Consumer Preference – For Study 5, the consumer preference study, one 60 µl application of 2% Floraesters 20 or 5% Canola Oil (and) Zea Mays (Corn) Starch (and) Silica, was applied to the back of each hand (one test article per hand) by the clinical staff. The subjects then used the opposite hand to rub each test article into the skin. A preference evaluation containing a list of various skin sensory and formula attributes were given to each subject immediately after application. Each subject was asked to choose which of the two formulas they preferred or to choose “no preference”. The skin attributes that were evaluated included skin moistness, skin suppleness, skin dryness/roughness, and skin smoothness. The formula attributes evaluated were greasiness, whiteness, and stickiness.

Data Analysis

The original data was captured on case report forms and then transferred to a Microsoft® Office Excel 2003 (Microsoft Corporation, Redmond, WA, USA) spreadsheet. Data was analyzed using GraphPad InStat 3 (GraphPad Software, Inc., La Jolla, CA).

For Studies 1 and 2 the Mann-Whitney Test (nonparametric, two-tailed p value) was used to determine any statistical significance ($p < 0.05$) using the raw data at baseline and the final evaluation time point for each test article. For Studies 3 and 4, the Kruskal-Wallis Test (nonparametric ANOVA) with the Dunn's Multiple Comparisons Post Test was used to determine any statistical significance ($p < 0.05$) between baseline and each evaluation time point for each test article.

The raw data was also used to calculate the percent improvement in SLS-induced TEWL (relative to the water control) in Studies 1 and 2, the percent barrier recovery from post-insult (untreated) back to baseline (pre-insult, untreated) for each measurement in Study 3, and the percent change in skin hydration from baseline for each evaluation time point for Study 4. In all cases, these changes were averaged for each subject. This data was then analyzed using GraphPad InStat 3. Statistical significance ($p < 0.05$) was determined between the various test articles at each evaluation time point using the Kruskal-Wallis Test (nonparametric ANOVA) with the Dunn's Multiple Comparisons Post Test. Outliers were removed from the mean percent changes using Chauvenet's Criterion for rejecting data.

For the consumer preference study, the original preference questionnaire data was transferred to a Microsoft® Office Excel 2003 spreadsheet, preference choices were tallied, and percent preference was calculated.

Results

Barrier Function (Pre-SLS Treatment) – The results of Studies 1 and 2 are depicted in Figures 1 and 2, respectively. In Study 1, the test article containing 2% Floraesters 60 produced the highest percent reduction in SLS-induced TEWL. This was followed by 5% petrolatum, 2% Floraesters 30, and 2% Floraesters 20. All formulas outperformed the vehicle ($p < 0.001$). There were no statistical differences among the test articles containing Jojoba Esters, or between the test articles containing Jojoba Esters and 5% petrolatum.

In Study 2, the dose response curve for Floraesters 60 (Figure 2) revealed that a maximum inhibition of SLS induced TEWL occurred at approximately 1.0% Floraesters 60. Additional increases in the concentration of Floraesters 60 did not produce additional efficacy. The test article containing 2.0% petrolatum inhibited the SLS induced TEWL approximately equal to that of the 1.0% Floraesters 60. The test articles containing 1.0% Floraesters 60, 1.5% Floraesters 60, and 2.0% Floraesters 60 along with the test article containing 2.0% petrolatum produced statistically significant decreases ($p < 0.001$) in TEWL over that of the vehicle.

Figure 1

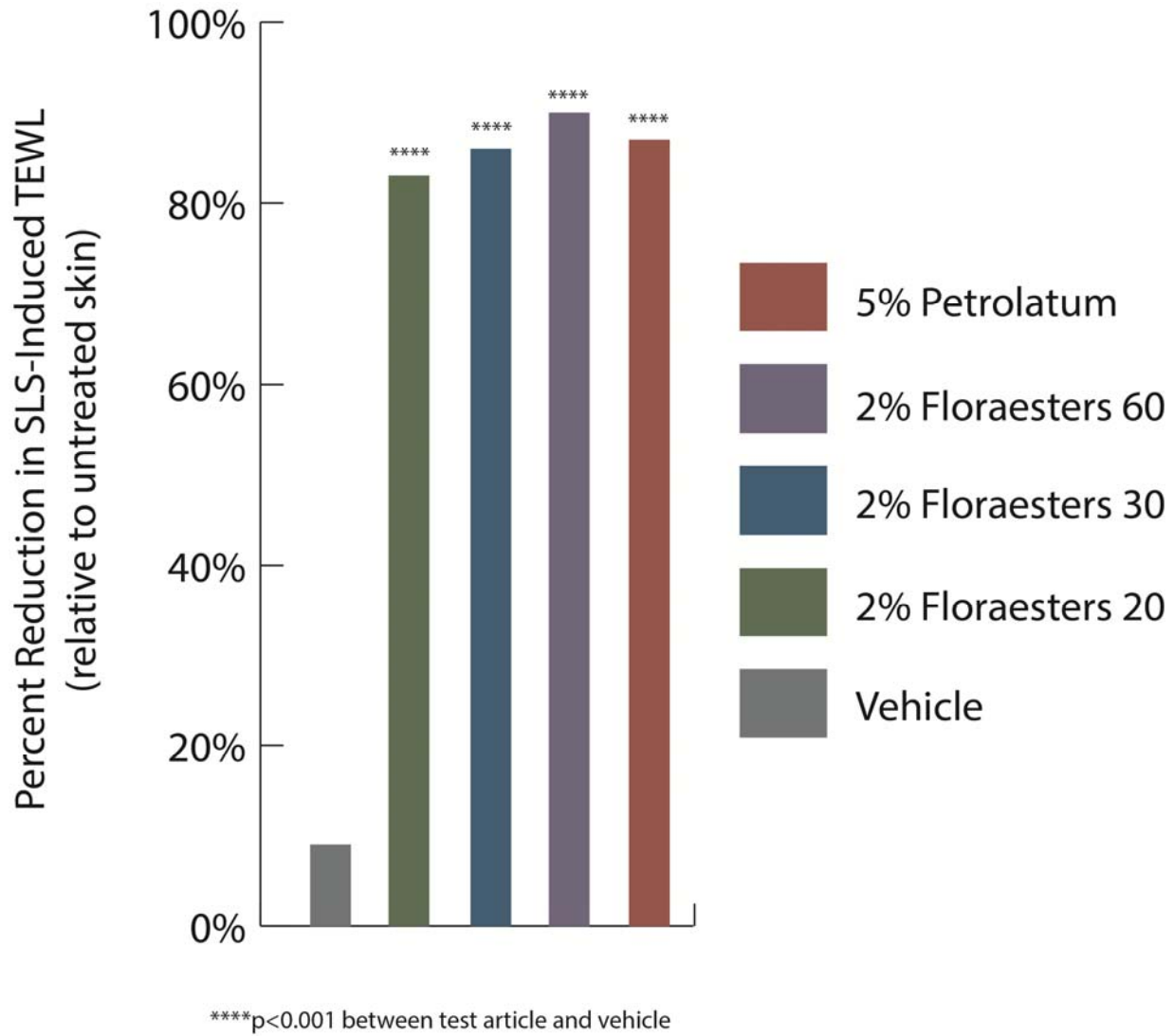
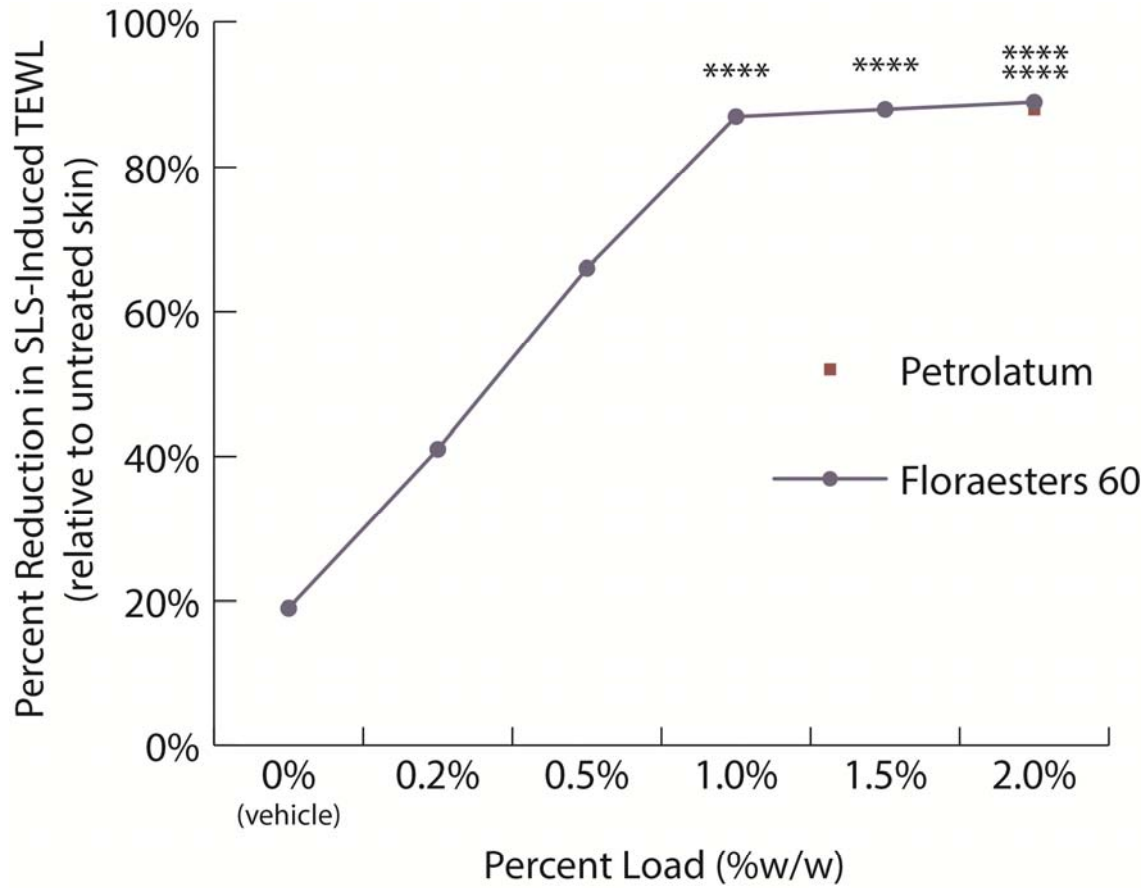


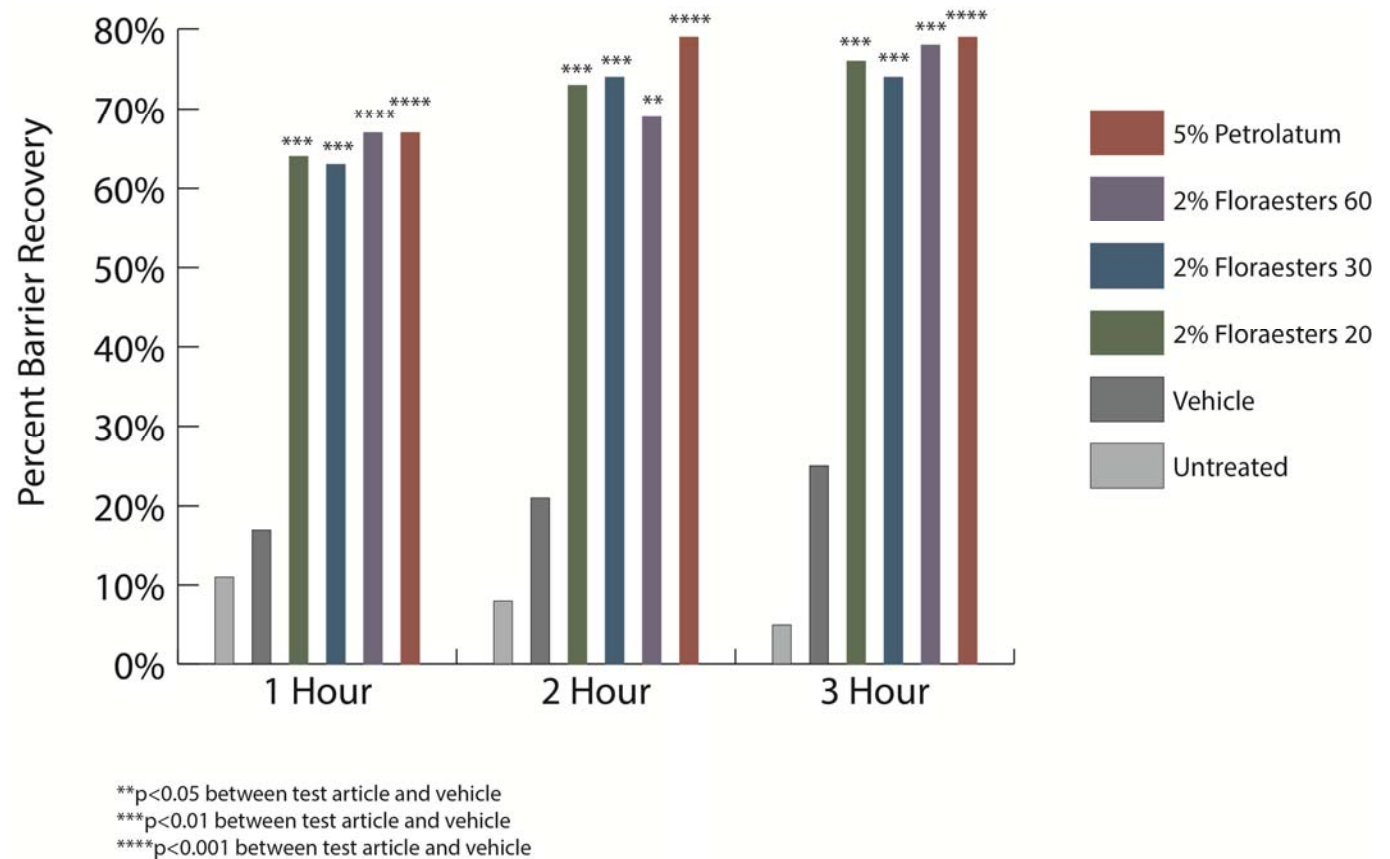
Figure 2



****p<0.001 between test article and vehicle

Barrier Recovery (Post-SLS Treatment) – The results of the skin barrier recovery study, Study 3, are depicted in Figure 3. The test articles containing 2% Floraesters 20, 2% Floraesters 30, and 2% Floraesters 60 produced percent barrier recoveries statistically equivalent ($p < 0.05$) to that of 5% petrolatum after one, two, and three applications. After three applications, the test article containing 5% petrolatum produced the greatest percent barrier recovery. This was followed closely, in order, by the test articles containing 2% Floraesters 60, 2% Floraesters 30, and 2% Floraesters 20. All formulas outperformed the vehicle ($p < 0.05$) at all time points.

Figure 3

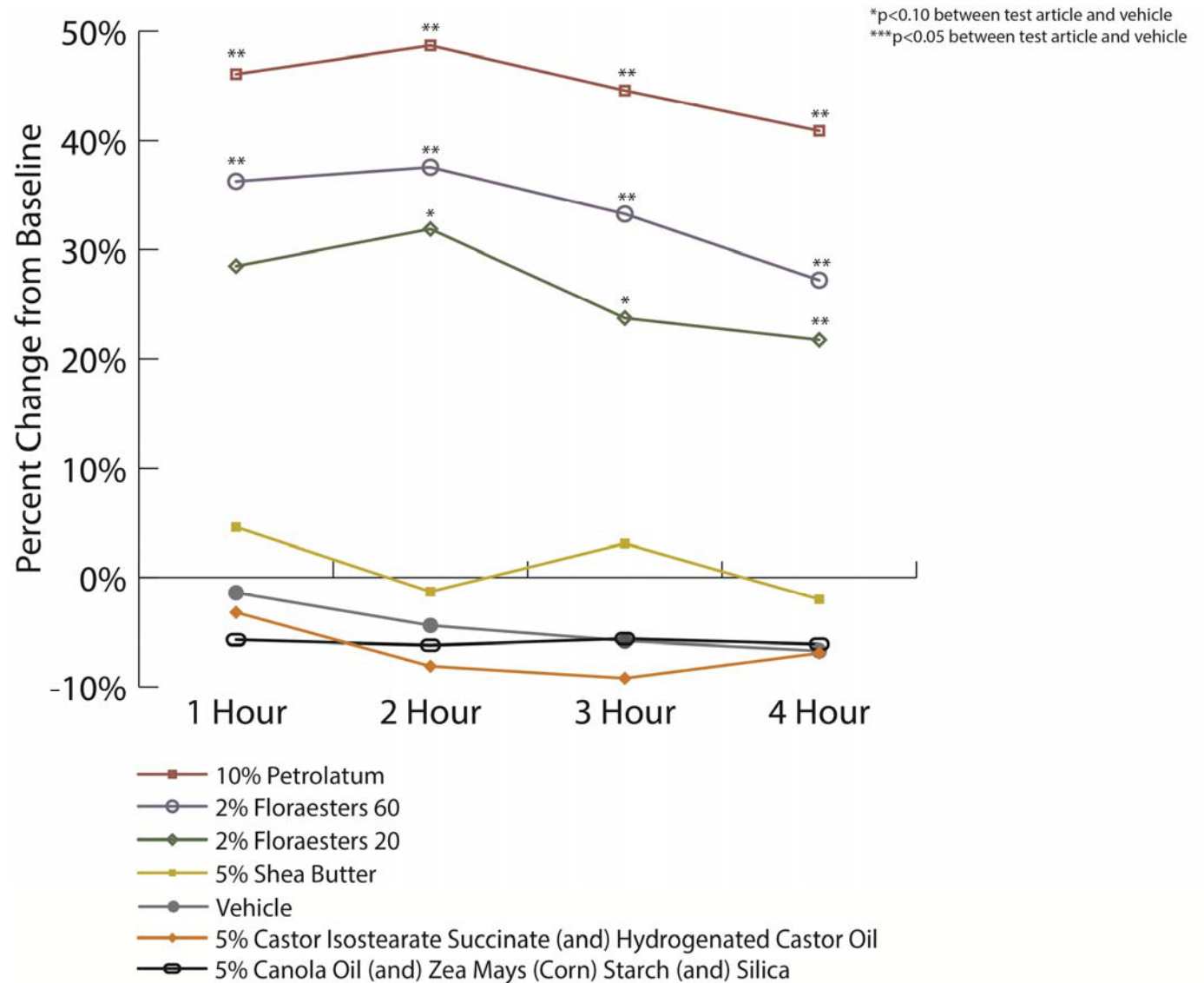


Skin Hydration – The results of the skin hydration study are depicted in Figure 4. The test article containing 2% Floraesters 60 produced higher Corneometer readings than any other test article (with the exception of the positive control, 10% petrolatum) at one, two, three, and four hours post test article application, with a peak increase in skin hydration at the two hour evaluation time point ($p<0.05$). In addition, this formula outperformed the vehicle, Castor Isostearate Succinate (and) Hydrogenated Castor Oil, and Canola Oil (and) Zea Mays (Corn) Starch (and) Silica at every evaluation time point ($p<0.05$).

Another test article, 2% Floraesters 20, produced a peak increase in Corneometer readings at the two hour evaluation time point. This formula outperformed the vehicle, Castor Isostearate Succinate (and) Hydrogenated Castor Oil, and Canola Oil (and) Zea Mays (Corn) Starch (and) Silica with directional significance ($p<0.10$) at most evaluation time points.

The three petrolatum-alternatives: Castor Isostearate Succinate (and) Hydrogenated Castor Oil (5.00%), Canola Oil (and) Zea Mays (Corn) Starch (and) Silica (5.00%) and *Butyrospermum parkii* (Shea Butter) (5.00%) produced minimal increases in skin hydration and did not achieve statistical significance from baseline at any evaluation time point.

Figure 4

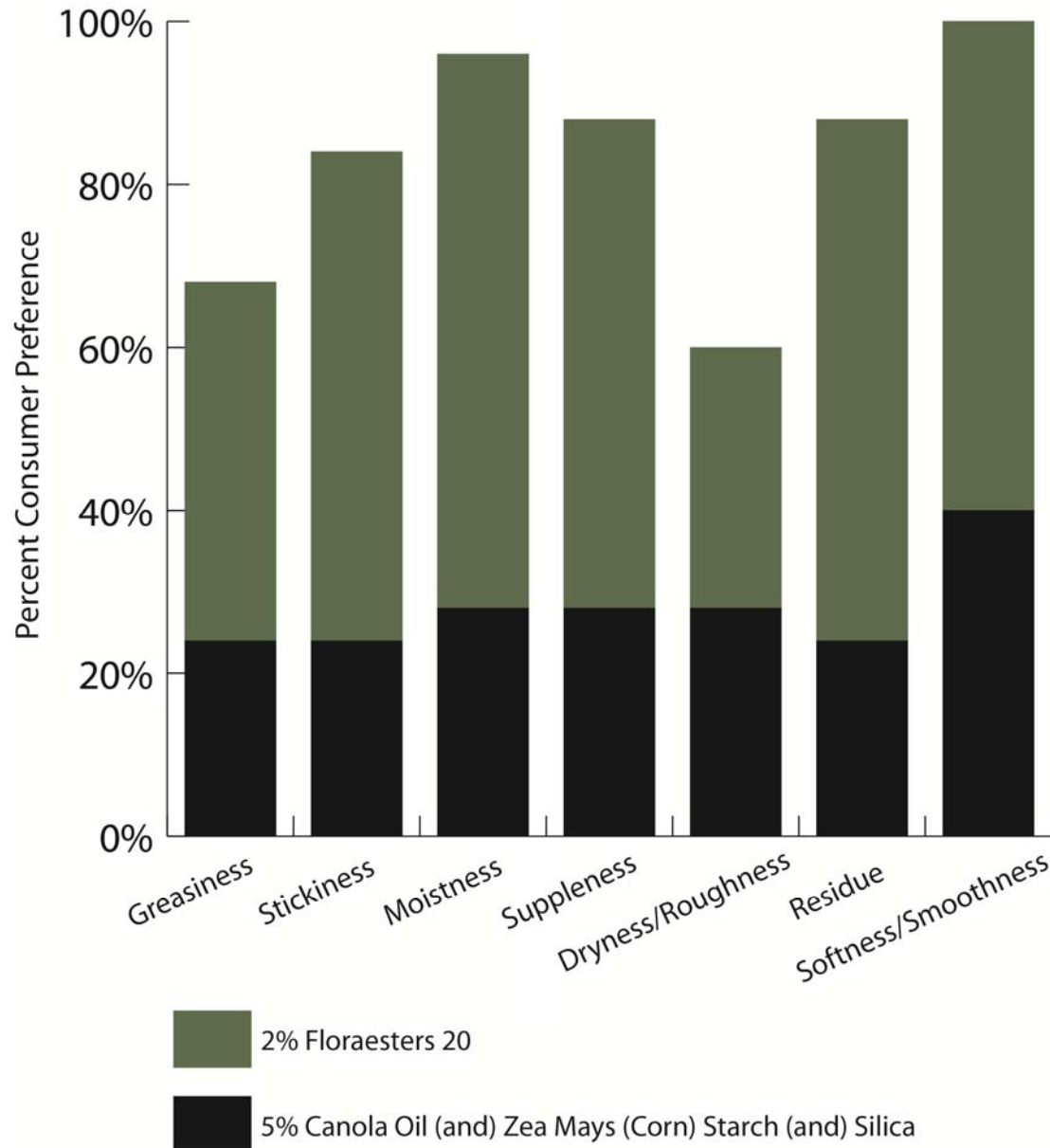


Consumer Preference – Sensory evaluations are often difficult to capture and do not always agree with bio-instrumental results. However, sensory evaluations are very important because consumers may ultimately decide which products to buy based on preferences rather than objective scientific measurements.

Two test articles from the skin hydration study were compared in a consumer preference study: 2% Floraesters 20 was compared to 5% Canola Oil (and) Zea Mays (Corn) Starch (and) Silica. Data from the preference study are depicted in Figure 5. The test article with 2% Floraesters 20 was preferred over the formula containing the marketed petrolatum-alternative ingredient by 68% of the subjects for moistness immediately after test article application. This supports the results of the skin hydration study which showed that 2% Floraesters 20 hydrated the skin better than the test article with this same marketed petrolatum-alternative ingredient.

More than twice as many consumers indicated that the formula containing 2% Floraesters 20 left the skin less sticky and less greasy than the lotion containing the marketed petrolatum-alternative ingredient. In addition, 68% of the subjects also indicated that the test article containing 2% Floraesters 20 left the skin more supple. The test article with 2% Floraesters 20 was also seen as less greasy than the test article containing the marketed petrolatum-alternative ingredient. In addition, the lotion containing 2% Floraesters 20 was perceived to produce more smooth/soft skin, less dry/rough skin, and left less of a residue on the skin than the lotion containing the marketed petrolatum-alternative ingredient.

Figure 5



CONCLUSIONS

The data presented in this paper show that specific Jojoba Esters with distinct melting points (*i.e.*, Floraesters 20, 30, and 60) have the capability of reducing damage to the skin barrier, as measured by TEWL, in a dose dependent manner. The data also suggests that these esters can

accelerate recovery of the skin barrier damaged by SLS, as well as provide the skin with the hydration necessary to maintain a healthy barrier. In addition, the barrier and skin hydration activity of these natural esters is similar to the activity of petrolatum.

It is not surprising that Jojoba Esters have beneficial effects on the skin. The predecessor of these esters, jojoba oil, has been used in folk remedies for sunburn, chaffed skin, and wounds.¹⁷ In 1995, Habashy *et.al.* reported the anti-inflammatory effects of jojoba liquid wax in a number of experimental models.¹⁸ More recently we have reported that another closely related class of Jojoba Esters (*i.e.*, hydrolyzed Jojoba Esters) were able to decrease TEWL and increase skin hydration in the presence of glycerin in patients with hand eczema.¹⁹ That same study also showed inhibition of staining for filaggrin and IL-6 by hydrolyzed Jojoba Esters.¹⁹

The mechanism of action of Floraesters 20, Floraesters 30, and Floraesters 60 has not been identified. The possibility that Jojoba Esters are acting like an occlusive agent similar to petrolatum is a definite possibility. However, another possibility is that these esters may influence cellular events associated with barrier function, thereby producing protective and restorative properties to the skin. Future research will explore the mechanism behind these biologically active molecules.

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Lipase-catalyzed Transesterification of Medium-chain Triacylglycerols and a Fully Hydrogenated Soybean Oil

Arnoldo Lopez-Hernandez, Hugo S. Garcia, Charles G. Hill Jr.

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ABSTRACT

A commercial preparation of medium-chain TAG (MCT) was enzymatically transesterified with a fully hydrogenated soybean oil (FHSBO) at different weight ratios (40:60, 50:50, 60:40, and 70:30). All reactions were carried out at 70 °C in flasks placed in an orbital shaker (300 rpm). Three different lipase preparations were tested: TLIM (*Thermomyces lanuginosus*), lipase PS (*Burkholderia cepacia*), and Chirazyme L2 (*Candida antarctica*). The progress of the reaction was monitored by following the changes in the triacylglycerol (TAG) profile of the reaction mixture with reversed-phase high-performance liquid chromatography (HPLC). The rates of disappearance of the TAG originally present in both the MCT and the FHSBO were fastest when lipase TL IM was used; the slowest rates were observed for lipase PS. Although the relative compositions of the newly formed TAG at equilibrium depended on the particular lipase used and the initial weight ratio of the substrates, the TAG families containing 2 stearic residues and a residue of either capric acid or caprylic acid were the most abundant product species. All samples were analyzed by differential scanning calorimetry (DSC) to determine the effect of this reaction on the melting profile of the resulting products.

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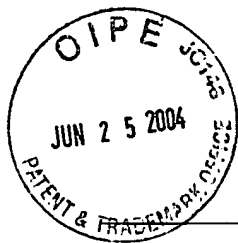
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PATENT

Case Docket No. ORYXE.001C2

Date: June 22, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Frederick L. Jordan
Appl. No. : 10/789,836
Filed : February 27, 2004
For : A MIXTURE FOR
TRANSDERMAL DELIVERY
OF LOW AND HIGH
MOLECULAR WEIGHT
COMPOUNDS
Examiner : Unassigned
Group Art Unit : Unassigned

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June 22, 2004

(Date)

Eric S. Furman, Ph.D., Reg. No. 45,664

TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application are:

- (X) An Information Disclosure Statement.
- (X) A PTO Form 1449 listing seventy-one (71) references, only of which twenty-nine (29) are enclosed.
- (X) The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.
- (X) Return prepaid postcard.

Eric S. Furman, Ph.D.
Registration No. 45,664
Attorney of Record
Customer No. 20,995
(619) 235-8550

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INFORMATION DISCLOSURE STATEMENT

Applicant : Frederick L. Jordan
App. No. : 10/789,836
Filed : February 27, 2004
For : A MIXTURE FOR TRANSDERMAL
DELIVERY OF LOW AND HIGH
MOLECULAR WEIGHT COMPOUNDS
Examiner : Unassigned
Group Art Unit : Unassigned

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed is form PTO-1449 listing seventy-one (71) references. References numbered 1-37, 43-45, 68 and 70 are of record in U.S. patent application No. 10/183,764, filed June 25, 2002, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Accordingly, copies of references numbered 1-37, 43-45, 68 and 70 are not submitted pursuant to 37 C.F.R. § 1.98(d). There are a total of twenty-nine (29) references that are enclosed. Those references are numbered 38-42, 46-67, 69 and 71.

This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required in accordance with 37 C.F.R. § 1.97(b)(3). If a first Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 6/22/04

By: 

Eric S. Furman, Ph.D.
Registration No. 45,664
Attorney of Record
Customer No. 20,995
(619) 235-8550

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FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
ORYXE.001C2APPLICATION NO.
10/789,836INFORMATION DISCLOSURE STATEMENT
BY APPLICANT

(USE SEVERAL SHEETS IF NECESSARY)

APPLICANT
Frederick L. JordanFILING DATE
February 27, 2004GROUP
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
	1	5,318,960	06/07/94	Toppo			
	2	5,431,924*	07/11/95	Ghosh et al.			
	3	5,472,713	12/05/95	Fein et al.			
	4	5,571,671	11/05/96	Potter			
	5	5,614,212	03/25/97	D'Angelo et al.			
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	19	92/08470	05/29/92	WO				
	20	97/09992 A1	03/20/97	WO				
	21	98/03163	01/29/98	WO				
	22	98/33474	08/06/98	WO				
	23	98/34629	08/13/98	WO				

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