

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Beetz et al.
U.S. Patent No.: 9,332,776 Attorney Docket No. 61529-0003IP1
Issue Date: May 10, 2016
Appl. Serial No.: 14/606,771
Filing Date: January 27, 2015
Title: METHODS AND APPARATUS FOR LOW HEAT SPRAY
DRYING

DECLARATION OF DAVE A. MILLER, PH.D.

I declare that all statements made herein on 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 under Section 1001 of Title 18 of the United States Code.

Date: July 9, 2026

By: 
Dr. Dave A. Miller

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I. ASSIGNMENT

1. I have been retained on behalf of McCormick & Company, Inc. (“Petitioner”) to offer technical opinions related to U.S. 9,332,776 (the “’776 patent”) (EX-1001). I understand that Petitioner is requesting that the Patent Trial and Appeal Board (“PTAB” or “Board”) institute an *inter partes* review (“IPR”) proceeding of the ’776 patent.

2. I have been asked to provide my independent analysis of the ’776 patent based on the prior art publications cited in this declaration.

3. I am not and never have been an employee of Petitioner. I received no compensation for this declaration beyond my normal hourly compensation based on my time actually spent analyzing the ’776 patent, the prior art publications cited below, and issues related thereto, and I will not receive any added compensation based on the outcome of any IPR or other proceeding involving the ’776 patent.

II. QUALIFICATIONS AND BACKGROUND INFORMATION

4. I am over the age of 18 and am competent to write this declaration. I have personal knowledge, or have developed knowledge of these technologies based upon education, training, or experience, of the matters set forth herein.

5. My qualifications are summarized here and explained in more detail in my curriculum vitae, which is attached as Appendix A to this report. Appendix A also includes a list of my publications and the cases in which I have testified at

deposition, hearing, or trial within the past four years.

6. I am the Chief Scientific Officer of AustinPx (formerly DisperSol Technologies, LLC), a pharmaceutical development and contract development and manufacturing organization in Georgetown, Texas, and I have more than twenty years of experience in pharmaceutical product development, with particular emphasis on the formulation and processing of poorly water-soluble and thermally sensitive active ingredients by techniques including spray drying, hot-melt extrusion, and other particle-engineering and encapsulation methods. I earned a Bachelor of Science in Chemical Engineering from The University of Texas at Austin in 2002 and a Doctor of Philosophy in Pharmaceutics from The University of Texas at Austin in 2007. My doctoral research, conducted under the supervision of Dr. James W. McGinity and Dr. Robert O. Williams III, addressed the improvement of oral absorption of poorly water-soluble drugs through advanced solid dispersion systems, and during that work I co-invented the KinetiSol processing technology. Before assuming my current role, I served as Vice President of Research and Development at DisperSol Technologies from 2011 to 2021, and earlier as a Principal Scientist and then Senior Principal Scientist at Hoffmann-La Roche, Inc., in Nutley, New Jersey, where my responsibilities included the formulation and process development of spray-dried and melt-extruded drug products. I have authored approximately thirty peer-reviewed journal articles and

numerous book chapters concerning pharmaceutical formulation, including chapters on spray drying technologies, and I am a co-editor of all three editions of the reference text *Formulating Poorly Water-Soluble Drugs* (AAPS/Springer, 2011, 2016, and 2022). I am a named inventor on numerous issued United States patents directed to drug-delivery and formulation technologies. I am a member of the American Association of Pharmaceutical Scientists and the Controlled Release Society, and I serve on the Editorial Advisory Board of AAPS PharmSciTech. Since 2023, I have also been retained as an independent expert in pharmaceutical patent litigation and arbitration matters involving formulation science, CMC development, amorphous solid dispersions, dissolution testing, and regulatory science. Further detail regarding my education, professional experience, publications, patents, honors, and prior expert engagements is set forth in my curriculum vitae, attached as Appendix A.

7. My curriculum vitae, included as an appendix to this declaration, includes a list of publications on which I am a named author. It contains further details regarding my experience, education, publications, and other qualifications to render an expert opinion in connection with this proceeding.

8. In writing this Declaration, I have considered the following: my own knowledge and experience, including my work experience in the formulation, spray drying, encapsulation, and particle engineering of active ingredients and in related

drying technologies; my experience in teaching and supervising others in those subjects; and my experience in working with others involved in those fields. In addition, I have analyzed the following publications and materials, in addition to other materials I cite in my declaration: the materials identified in the List of Exhibits accompanying the Petition, namely the following:

- a. U.S. Patent No. 9,332,776 (“the ’776 patent”) (EX-1001);
- b. Prosecution History of the ’776 patent (EX-1002);
- c. Subramaniam et al., EP 1,435,797 B1 (“Subramaniam”) (EX-1004);
- d. Baranauskienė et al., 55 J. Agric. Food Chem. 3027 (2007) (“Baranauskiene”) (EX-1005);
- e. Watanabe et al., U.S. Patent App. Pub. No. 2004/0228959 A1 (“Watanabe”) (EX-1006);
- f. R.P. Singh, *Scientific Principles of Shelf Life Evaluation*, in *Shelf Life Evaluation of Foods 3* (C.M.D. Man & A.A. Jones eds., 1st ed. 1994) (“Singh”) (EX-1007);
- g. ICH Harmonised Tripartite Guideline Q1A(R2) (2003) (“ICH Q1A(R2)”) (EX-1008);
- h. FDA Guidance for Industry Q1A(R2) (2003) (“FDA Q1A(R2)”) (EX-1009);
- i. Hagemann et al., U.S. Patent No. 4,663,068 (1987) (“Hagemann”) (EX-1010);
- j. Bechoff et al., 121 Food Chemistry 348 (2010) (“Bechoff”) (EX-1012);
- k. Labuza, *Shelf-Life Dating of Foods* (1982) (“Labuza”) (EX-1013);
- l. Palma, *Extraction of Capsanthin from Paprika Flakes* (M.S. thesis, Univ. of Chile 2013) (“Palma”) (EX-1014);
- m. Jennings, U.S. Patent No. 5,723,424 (1998) (“Jennings”) (EX-1015);

- n. EMEA/HMPC, Community Herbal Monograph on *Mentha × piperita* L., aetheroleum (2007) (“EMA Monograph”) (EX-1016);
- o. Aetheroleum *Menthae Piperitae*, in WHO Monographs on Selected Medicinal Plants, Vol. 2 (2002) (“WHO Monograph”) (EX-1017);
- p. Deli et al., 49 J. Agric. Food Chem. 1517 (2001) (“Deli”) (EX-1018);
- q. Topuz & Özdemir, 20 J. Food Composition & Analysis 596 (2007) (“Topuz 2007”) (EX-1019);
- r. Grigoleit & Grigoleit, 12 Phytomedicine 612 (2005) (“Grigoleit”) (EX-1020);
- s. Hornero-Méndez & Mínguez-Mosquera, 49 J. Agric. Food Chem. 3584 (2001) (“Hornero-Méndez”) (EX-1021);
- t. Britton, Liaaen-Jensen & Pfander (eds.), Carotenoids, Vol. 1B: Spectroscopy (1995) (“Britton”) (EX-1022);
- u. Jarén-Galán & Mínguez-Mosquera, 47 J. Agric. Food Chem. 4379 (1999) (“Jarén-Galán”) (EX-1023);
- v. Pérez-Gálvez & Mínguez-Mosquera, 49 J. Agric. Food Chem. 4864 (2001) (“Pérez-Gálvez 2001”) (EX-1024);
- w. Pérez-Gálvez & Mínguez-Mosquera, 1569 Biochimica et Biophysica Acta 31 (2002) (“Pérez-Gálvez 2002”) (EX-1025);
- x. Topuz & Özdemir, 51 J. Agric. Food Chem. 4972 (2003) (“Topuz 2003”) (EX-1026);
- y. Topuz, 41 LWT – Food Science and Technology 1672 (2008) (“Topuz 2008”) (EX-1027);
- z. Shin et al., 66 J. Food Sci. 15 (2001) (“Shin”) (EX-1028);
- aa. Mínguez-Mosquera & Jarén-Galán, 67 J. Sci. Food & Agric. 153 (1995) (“Mínguez-Mosquera”) (EX-1029);
- bb. Pérez-Gálvez, Ríos & Mínguez-Mosquera, 53 J. Agric. Food Chem. 4820 (2005) (“Pérez-Gálvez 2005”) (EX-1030);
- cc. Ríos et al., 106 Food Chemistry 1145 (2008) (“Ríos”) (EX-1031);

- dd. Pybus & Sell (eds.), *The Chemistry of Fragrances* (1999) (“Pybus”) (EX-1032);
- ee. Paprika Extract, in *FAO JECFA Monographs 5*, at 51 (69th mtg., Rome 2008) (“JECFA Monograph”) (EX-1033);
- ff. Cantrill, *Paprika Extract: Chemical and Technical Assessment (CTA)*, prepared for the 69th JECFA (2008) (“JECFA CTA”) (EX-1034).
- gg. Scanlon & Willis, 23 *J. Chromatogr. Sci.* 333 (1985) (“Scanlon & Willis”) (EX-1035).
- hh. Furia & Bellanca (eds.), *Fenaroli’s Handbook of Flavor Ingredients*, Vol. II (2d ed. 1975) (“Fenaroli’s”) (EX-1036);
- ii. ACS Record (American Chemical Society Publications Record for Baranauskiene et al., 55 *J. Agric. Food Chem.* 3027 (2007), DOI 10.1021/jf062508c (published online Mar. 24, 2007; published in issue Apr. 1, 2007), available at <https://pubs.acs.org/doi/10.1021/jf062508c>) (EX-1037)
- jj. PubMed Record (U.S. National Library of Medicine, MEDLINE/PubMed Record for Baranauskiene et al. (PMID 17381102), available at <https://pubmed.ncbi.nlm.nih.gov/17381102/>) (EX-1038)
- kk. Food & Agriculture Organization of the United Nations, Document Repository Record for Compendium of Food Additive Specifications, *FAO JECFA Monographs 5* (Rome 2008), FAO Doc. No. i0345e, available at <https://www.fao.org/4/i0345e/i0345e00.htm> (“FAO Repository Record”) (EX-1039)
- ll. Food & Agriculture Organization of the United Nations, JECFA Online Database of Food Additive Specifications, available at <https://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/> (“JECFA Database”) (EX-1040)
- mm. Bibliography of select publications citing Baranauskiene et al. (2007) identified via the Google Scholar (“Baranauskiene Cited-By Bibliography”) (EX-1041).
- nn. Baranauskiene Cited-By Bibliography on Google Scholar (bibliography of publications citing Baranauskiene et al., 55 *J. Agric. Food*

Chem. 3027 (2007) (available at https://scholar.google.com/scholar?cites=12531058245374932528&as_sdt=5,33&scioldt=0,33&hl=en) (EX-1042)

oo.FAO guidelines on the structure and content of the document called “Chemical and Technical Assessment (CTA)” (available at https://www.fao.org/fileadmin/templates/agns/pdf/jecfa/2003-02-24_CTA.pdf) (EX-1043)

9. I have reviewed the ’776 patent (EX-1001), and relevant excerpts of the prosecution history (EX-1002) of the ’776 patent. Among various textbooks, documents, and publications, I have also reviewed the following prior art references: Subramaniam (EX-1004); Baranauskiene (EX-1005); Watanabe (EX-1006); the JECFA Monograph (EX-1033); and the JECFA CTA (EX-1034); together with the additional technical and scientific references identified in the List of Exhibits (EX-1007 to EX-1043).

10. Counsel (Fish & Richardson) has informed me that I should consider these materials through the lens of one of ordinary skill in the art related to the ’776 patent at the time of the earliest possible priority date of the ’776 patent, and I have done so during my review of these materials. I have been informed by Counsel to use the date of September 27, 2010, as the Priority Date.

11. I have no financial interest 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.

12. My opinions, as explained below, are based on my education,

experience, and expertise in the fields relating to the '776 Patent. Unless otherwise stated, my testimony below refers to the knowledge of one of ordinary skill in the art as of the earliest possible priority date. Any figures that appear within this document have been prepared with the assistance of Counsel and reflect my understanding of the '776 Patent and the prior art discussed below.

III. OVERVIEW OF CONCLUSIONS FORMED

13. This declaration explains the conclusions that I have formed based on my analysis of all of the materials considered and my personal experience. To summarize those conclusions, based upon my knowledge and experience and my review of the prior art references listed above, I believe that: (a) each of Baranauskiene (EX-1005), Watanabe (EX-1006), and Subramaniam (EX-1004) is analogous prior art in the same field of endeavor as the '776 patent—the spray drying of flavors, fragrances, pigments, and/or other active ingredients encapsulated within a carrier to form dried powders—and each is reasonably pertinent to the problems of retention and stability that the '776 patent addresses; (b) Baranauskiene renders obvious claims 1–5 and 7–9; (c) Watanabe, in view of the JECFA References (EX-1033, EX-1034), renders obvious claims 10–11, 15–17, and 19; and (d) Subramaniam renders obvious claims 1–5, 7–14, and 16–19. The bases for these opinions are set forth in the sections that follow.

14. In support of these conclusions, I provide an overview of the references

in Section IX and more detailed comments regarding the obviousness of claims 1-5 and 7-19 (“the Challenged Claims”) of the ’776 patent in Section X.

IV. LEVEL OF ORDINARY SKILL IN THE ART

15. In my opinion, one of ordinary skill in the art relating to, and at the time of, the Priority Date would have been someone with (1) at least a bachelor’s degree in chemical engineering, chemistry, pharmaceutical science, food science, or a related field, and (2) at least three years of experience in the formulation, spray drying, or encapsulation of pharmaceutical, food, flavor, fragrance, or pigment compositions (“POSITA”). Additional education could substitute for professional experience, and vice versa.

16. Further, all positions in this declaration are from the vantage point of a POSITA as of the Priority Date, September 27, 2010.

17. Based on my experiences, I have a good understanding of the capabilities of a POSITA. Indeed, I have taught, participated in organizations, and worked closely with many such persons over the course of my career. Based on my knowledge, skill, and experience, I understand the capabilities of a POSITA. For example, from my industry experience, I am familiar with what a POSITA would have known and found predictable in the art. From teaching and supervising my post-graduate students, I also understand the knowledge that a person with this academic experience possesses. Furthermore, I possess those capabilities myself.

V. LEGAL STANDARDS

A. Terminology

18. 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). The '776 patent was filed January 27, 2015 (as U.S. Application No. 14/606,771), and claims priority to the September 27, 2010 filing date of U.S. Provisional Patent Application No. 61/386,762 (through U.S. Application No. 13/245,369, filed September 26, 2011, of which the application that issued as the '776 patent is a continuation-in-part), which I refer to as the "Critical Date" or "Priority Date" in this proceeding. Because I do not know at what date the invention as claimed was made, if ever, I have used the Critical Date of the '776 patent as the point in time for claim interpretation purposes. My opinion does not change if the invention date is earlier.

B. Public Availability

Baranauskiene (EX-1005) Was Publicly Accessible Before September 27, 2010

19. I understand that a reference qualifies as a "printed publication" if it

was sufficiently accessible to persons interested and ordinarily skilled in the relevant art, exercising reasonable diligence, before the priority date of the challenged patent. Based on my review, Baranauskiene (EX-1005) was publicly accessible before the September 27, 2010, priority date of the '776 patent.

20. Baranauskiene is a peer-reviewed research article titled *Flavor Retention of Peppermint (Mentha piperita L.) Essential Oil Spray-Dried in Modified Starches during Encapsulation and Storage*, which appeared in the *Journal of Agricultural and Food Chemistry*, a periodical published by the American Chemical Society. EX-1005, 3027. In my experience, the *Journal of Agricultural and Food Chemistry* is one of the principal peer-reviewed journals in the fields of food science and flavor encapsulation, and it is routinely read, subscribed to, and relied upon by researchers working in this area. As of 2007, a person of ordinary skill in the art would have had ready access to this journal through institutional and university library subscriptions, personal subscriptions, and standard online and abstracting databases.

21. The face of the reference reflects that it was published in 2007. It appears at volume 55, issue 8, pages 3027–3036, bears the copyright notice “© 2007 American Chemical Society,” and is assigned the digital object identifier 10.1021/jf062508c. EX-1005, 3027. The reference states on its first page that it was “Published on Web 03/24/2007,” and its printed editorial history states that it was

received for review on September 1, 2006, revised on February 10, 2007, and accepted on February 17, 2007. EX-1005, 3027, 3036.

22. I have confirmed these publication dates against independent records. The American Chemical Society's own publication record for this article reports that it was published online on March 24, 2007, and published in the print issue on April 1, 2007. EX-1037. The article is also indexed in the U.S. National Library of Medicine's MEDLINE/PubMed database under PMID 17381102, which lists the same volume, issue, page range, and DOI, and records an online-publication date of March 24, 2007. EX-1038. The article is further indexed in Web of Science and Chemical Abstracts Service, and I have observed it cited in numerous subsequent publications in this field. EX-1041; EX-1042.

23. Based on the foregoing, it is my opinion that Baranauskiene was published, distributed to subscribers, and indexed in publicly available databases in 2007—more than three years before the September 27, 2010, priority date of the '776 patent. A person of ordinary skill in the art interested in flavor encapsulation and spray drying, exercising reasonable diligence, would have been able to locate and obtain Baranauskiene well before September 27, 2010.

JECFA Monograph (EX-1033) Was Publicly Accessible Before September 27, 2010

24. I understand that a reference qualifies as a “printed publication” if it was sufficiently accessible to persons interested and ordinarily skilled in the relevant

art, exercising reasonable diligence, before the priority date of the challenged patent. Based on my review, JECFA Monograph (EX-1033) was publicly accessible before the September 27, 2010, priority date of the '776 patent.

25. The JECFA Monograph is *FAO JECFA Monographs 5, Compendium of Food Additive Specifications*, published by the Food and Agriculture Organization of the United Nations (FAO) in Rome in 2008. EX-1033, title page. On its face, it bears the International Standard Book Number (ISBN) 978-92-5-106065-0, identifies itself as a volume in FAO JECFA Monographs series (ISSN 1817-7077), and bears the copyright notice “© FAO 2008.” *Id.*, title page & verso. In my experience, the FAO JECFA Monographs are a standard, widely relied-upon reference series in the fields of food additives, food chemistry, and food ingredient specifications, and the specifications of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) are routinely consulted by researchers and technologists working in those fields. As of 2008, a person of ordinary skill in the art would have had ready access to this publication through institutional and university libraries, through FAO’s and WHO’s public document repositories, and through FAO’s online searchable database of JECFA specifications.

26. The volume states, in its Introduction, that it contains the specifications of identity and purity prepared at the 69th meeting of JECFA, held in Rome on June 17–26, 2008. EX-1033, ix. The specification for Paprika Extract appears at page 51

and states on its face that it comprises new tentative specifications prepared at the 69th JECFA (2008) and published in FAO JECFA Monographs 5 (2008).¹ *Id.*, 51. The volume also directs readers to FAO’s online JECFA specifications database and archive as public access points for the monographs. *Id.*, 51, ix.

27. FAO publishes these specifications as numbered volumes in the FAO JECFA Monographs series and makes them available to the public both in printed form and through FAO’s online JECFA specifications database, which is organized by the name of the food additive (e.g., a search for “paprika extract” returns the corresponding specification). The present volume reflects this practice on its face. Additionally, FAO maintains the volume in its public document repository under document symbol i0345e, where it is identified as *FAO JECFA Monographs 5* (Rome, 2008), bears the same ISBN, and is available in full for public download. EX-1039. The verso of the volume expressly authorizes reproduction and dissemination of the material for educational and other non-commercial purposes without prior permission. *Id.* And FAO separately maintains an online searchable

¹“Tentative” here reflects JECFA’s administrative process of awaiting additional commercial-batch data on two specific impurity/composition parameters and a pending toxicological (ADI) determination, it does not mean the identity, extraction methods, or chemical characterization were provisional or unreliable.

database in which each JECFA specifications monograph is provided in PDF format for public review and printing. EX-1040.

28. Based on the foregoing, it is my opinion that the JECFA Monograph was published by FAO in 2008 and distributed under an ISBN—more than two years before the September 27, 2010, priority date of the '776 patent—and that FAO makes the volume publicly available both in print and through its online JECFA specifications database and public document repository. A person of ordinary skill in the art interested in the composition, specifications, or stability of paprika extract and its carotenoid pigments, exercising reasonable diligence, would have been able to locate and obtain the JECFA Monograph well before September 27, 2010.

JECFA CTA (EX-1034) Was Publicly Accessible Before September 27, 2010

29. I understand that a reference qualifies as a “printed publication” if it was sufficiently accessible to persons interested and ordinarily skilled in the relevant art, exercising reasonable diligence, before the priority date of the challenged patent. Based on my review, JECFA CTA (EX-1034) was publicly accessible to a person of ordinary skill in the art before the September 27, 2010, priority date of the '776 patent.

30. The JECFA CTA is a document titled “Paprika Extract — Chemical and Technical Assessment (CTA),” prepared by Richard Cantrill, Ph.D., for the 69th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

EX-1034, 1. The first page bears the running head “69th JECFA – Chemical and Technical Assessment (CTA), 2008,” and each of the document’s eleven pages is footed with the designation “Paprika extract (CTA) 2008.” *Id.*, 1–11. The 69th JECFA meeting was held in Rome on June 17–26, 2008. The electronic file properties of the document identify it as a final version prepared on September 23, 2008, and list its author as “wennberg,” corresponding to Dr. Annika Wennberg, the FAO Joint Secretary to the 69th JECFA. EX-1034 (file properties).

31. The public availability of the JECFA CTA as of 2008 is confirmed by the JECFA Monograph. The JECFA Monograph—*FAO JECFA Monographs 5*, which was itself published and publicly available in 2008—states in its Introduction that Chemical and Technical Assessments were prepared as background documentation for the 69th meeting and that “[t]hese documents are available online” at the FAO JECFA technical-assessments archive. EX-1033, ix. The JECFA CTA is one of those background documents: it was prepared by Dr. Cantrill for the same 69th meeting, is designated “Paprika extract (CTA) 2008” on its face, and concerns the same paprika extract addressed in the specification prepared at the 69th JECFA. EX-1034, 1; EX-1033, 51. In my experience, the Chemical and Technical Assessments prepared for JECFA are published by the Food and Agriculture Organization of the United Nations (FAO) on its public website as part of the Committee’s risk-assessment process, and they are routinely consulted by

researchers and technologists working on the identity, composition, and properties of food additives and colors. Because the JECFA Monograph (EX-1033) was publicly available in 2008 and directed the public to the online CTAs, a person of ordinary skill in the art exercising reasonable diligence would have been able to locate and obtain the JECFA CTA as of that time.

32. FAO continues to make the JECFA CTA publicly available. FAO hosts the identical eleven-page assessment prepared by Dr. Cantrill for the 69th JECFA in the technical-assessments section of its official website. EX-1034. Furthermore, it is my understanding that the FAO made Chemical and Technical Assessments publicly available on the internet. In February 2003, the FAO Joint Secretariat issued official guidelines on the structure and content of the CTA, explicitly stating the intention of making CTAs publicly available. *See* EX-1043. As detailed on page 2 of those guidelines under the “Publication policy” section, the Secretariat noted that because “all other Committee deliberations are publicly available, it was decided to make the *Chemical and Technical Assessments* available, as well.” *Id.* at 2. The policy further states that this new publication policy will be enforced from the 61st meeting onwards and that the CTAs will be available for download at the FAO JECFA website. *Id.* Because the Paprika Extract CTA was prepared for the 69th JECFA meeting, it was subject to this publication policy. Based on this official directive, it would be routine practice of the FAO to upload these finalized background

documents to its public-facing web archive shortly after they are prepared. Accordingly, the FAO would have made the Paprika Extract CTA publicly accessible on its website shortly after it was finalized in September 2008, well before the September 27, 2010, priority date.

33. Based on the foregoing, it is my opinion that the JECFA CTA was prepared for the 69th JECFA, finalized in 2008, and that—as confirmed by the contemporaneous FAO JECFA Monographs 5 (EX-1033), which was itself publicly available in 2008 and directed the public to the online Chemical and Technical Assessments prepared for that meeting—the JECFA CTA was made publicly available by FAO as 69th-meeting background documentation in 2008, more than two years before the September 27, 2010 priority date of the '776 patent. A person of ordinary skill in the art interested in the composition, chemistry, or color properties of paprika extract and its carotenoid pigments, exercising reasonable diligence, would have been able to locate and obtain the JECFA CTA well before September 27, 2010.

C. Legal Standards

34. I have been informed by Counsel and understand that documents and materials that qualify as prior art can render a patent claim unpatentable as being anticipated or obvious.

35. I am 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 anticipated or rendered obvious.

D. Anticipation

36. I understand that patents or printed publications that qualify as prior art can be used to invalidate a patent claim as anticipated or as obvious.

37. I understand that, once the claims of a patent have been properly construed, the second step in determining anticipation of a patent claim requires a comparison of the properly construed claim language to the prior art on a limitation-by-limitation basis.

38. I understand that a prior art reference “anticipates” an asserted claim, and thus renders the claim invalid, if all limitations of the claim are disclosed in that prior art reference, either explicitly or inherently (i.e., necessarily present).

E. Obviousness

39. I understand that even if a patent is not anticipated, it is still invalid if the differences between the claimed subject matter 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 POSITA.

40. I have been informed by Counsel and understand that a claim is unpatentable for obviousness and that obviousness may be based upon a

combination of references. I am 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 am 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.

41. I am informed by Counsel and understand that when a patented invention is a combination of known elements, a court determines 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.

42. I am 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 am informed by Counsel 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 am 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.”

43. I am 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 prior art and the claims, (3) the level of ordinary skill in the art, and (4) any so called “secondary considerations” of non-obviousness, which include: (i) “long felt need” for the claimed invention, (ii) commercial success attributable to the claimed invention, (iii) unexpected results of the claimed invention, and (iv) “copying” of the claimed invention by others.

44. I have been informed by Counsel and understand that an obviousness evaluation can be based on a single reference or 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.

45. 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.

46. 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 considers the inferences and creative steps that a person of ordinary skill would have employed at the time of invention.

47. 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.

48. 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.

49. I have been informed by Counsel and understand that, in assessing

obviousness in light of a single reference, that reference is not read in isolation but is understood as a person of ordinary skill in the art would have understood it—that is, in light of the ordinary knowledge, skill, and background understanding possessed by such a person as of the priority date. I understand that this background knowledge includes what was generally known in the field and what was set out in standard, authoritative references that a person of ordinary skill would have been aware of and would have consulted as a matter of ordinary practice. I have been informed by Counsel and understand that, in this respect, background or reference materials may be used to show the knowledge a person of ordinary skill in the art would have brought to bear in understanding a primary reference.

50. 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.

51. 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).

VI. MATERIALS CONSIDERED

52. My analysis and conclusions set forth in this declaration are based on my educational background and experiences in the field (*see* Section II). Based on my knowledge and experience, I am considered to be an expert in the field. Also, based on my knowledge and experience, I understand and know of the capabilities of persons of ordinary skill in the field around the Critical Date, and I taught, participated in organizations, and worked closely with many such persons in the field during that time frame.

53. As part of my independent analysis for this declaration, I have considered the following: the background knowledge/technologies that were commonly known to persons of ordinary skill in this art during the time before the Critical Date; my own knowledge and experiences gained from my work experience in the field of the '776 patent and related disciplines; and my experience in working with others involved in this field and related disciplines.

54. In addition, I have analyzed the publications and materials listed above.

55. My analysis and conclusions set forth in this declaration are based on the perspective of a POSITA.

VII. TECHNOLOGY OVERVIEW

56. In this section I provide an overview of the relevant technology and

state of the technical community before the Critical Date. This description is not intended to be exhaustive, but to provide sufficient background to support and contextualize my analysis below.

A. Spray Drying and Encapsulation

57. Spray drying is a well-established unit operation that has been used for decades to convert a liquid feed into a dry, free-flowing powder. In the flavor, fragrance, food, and pharmaceutical fields, the active ingredient to be dried is typically combined with one or more carrier materials—commonly carbohydrates such as maltodextrin, modified food starch, gum arabic, sucrose, or similar matrix formers—and dissolved, dispersed, or emulsified in water or other suitable solvent to form a solution, emulsion, or slurry. That feed is atomized into fine droplets and contacted with a stream of heated drying gas, which rapidly evaporates the water and leaves solid particles in which the active ingredient is entrapped within a solidified carrier matrix. This entrapment is what the art refers to as encapsulation. In my more than twenty years of formulating and drying thermally sensitive and volatile active ingredients by spray drying and related particle-engineering techniques, I have carried out and evaluated this process many times, and its principles were well understood by those of ordinary skill in the art well before the Critical Date.

58. A principal purpose of encapsulating an active ingredient in a spray-

dried carrier is to preserve the active ingredient—both during the drying step itself and during the storage that follows. A well-formed carrier matrix immobilizes the active ingredient within each particle and shields it from the agents that would otherwise cause loss or degradation, including heat, oxygen, moisture, and light, and it also retards the escape of volatile constituents. Two distinct performance questions therefore arise for any such powder, and they map onto the two independent claims of the '776 patent: first, how faithfully the active ingredient's composition survives the conversion of the liquid feed into the dry powder (which I refer to as “retention”); and second, how well that composition is preserved thereafter, as the powder is stored (which I refer to as “stability”). I address each in turn because the '776 patent's claims are framed in these terms.

B. Retention of an Active Ingredient Through Spray Drying

59. Many active ingredients of commercial interest—including essential oils, flavors, and fragrances—are not single compounds but mixtures of many individual molecular constituents, each contributing to the overall flavor or aroma. Because these constituents differ in volatility and other physical properties, the drying step can affect them unequally: more volatile components may be lost preferentially during atomization and evaporation, which shifts the relative proportions of the constituents in the recovered active ingredient. “Retention,” as I use the term, refers to the degree to which the composition of the active ingredient

recovered from the dried powder matches the composition of the active ingredient as originally loaded into the feed. A person of ordinary skill in the art assessing retention would compare, for a given constituent, its weight percentage of the active ingredient before drying against its weight percentage after drying; the smaller the change, the higher the retention. Independent claim 1 of the '776 patent captures exactly this comparison, requiring that the weight percentage of a principle molecular type in the final (recovered) active ingredient be within about 5% of its weight percentage in the initial active ingredient. EX-1001, claim 1.

60. The composition of such a mixture, and thus the weight percentage of any given constituent, is routinely determined by well-known analytical methods—most commonly gas chromatography, frequently with flame-ionization detection, and, for colored constituents such as pigments, spectrophotometry. These techniques, and the practice of expressing an individual constituent as a percentage of the active ingredient as a whole, were standard and well within the ordinary skill in the art well before the Critical Date.

C. Stability of an Active Ingredient During Storage

61. Even after an active ingredient has been successfully dried and encapsulated, its composition can change over time during storage. Individual constituents may be lost or converted through processes such as oxidation, isomerization, hydrolysis, and slow volatilization, and the rates of these processes

depend on conditions including temperature, moisture (water activity), oxygen availability, and light exposure. “Stability,” as I use the term, refers to the degree to which the composition of the encapsulated active ingredient is preserved during storage. A person of ordinary skill in the art assessing stability would measure the change in a constituent’s weight percentage over a defined storage period at a defined temperature. Independent claim 10 of the ’776 patent captures this measure, requiring that the weight percentage of a principle molecular type not vary by more than about 5% during aging of the dried powder at an elevated temperature of about 95°F for periods up to about 1,000 hours. EX-1001, claim 10.

62. Because observing degradation under ordinary storage conditions in real time can take months or years, it was long-established practice before the Critical Date to evaluate stability by accelerated testing—storing the material at one or more elevated temperatures and measuring the resulting loss over a shorter period—and then to project the behavior at a milder condition or a longer time using standard chemical-kinetics tools. In particular, the degradation of many food, flavor, and pigment constituents follows first-order (or pseudo-first-order) kinetics, in which a constant fraction of the remaining constituent is lost per unit time, and the dependence of the reaction rate on temperature is described by the Arrhenius relationship, commonly expressed for practitioners through the Q10 factor (the factor by which a reaction rate changes for a 10°C change in temperature). EX-1007;

EX-1008; EX-1013. These principles allow a person of ordinary skill to take a loss measured in an accelerated test and reliably estimate the loss that would occur at a lower temperature or over a different period. I apply these same well-established tools in my analysis below.

63. In short, retention and stability are two long-recognized measures of how well a spray-dried, encapsulated active ingredient preserves its composition—through the drying step and through subsequent storage, respectively—and both the measurement techniques and the predictive tools I have described were well within the knowledge of a person of ordinary skill in the art before the Critical Date. The '776 patent expresses these familiar measures quantitatively, through the weight percentage of a “principle molecular type” of the active ingredient. In the sections that follow, I apply these concepts and tools to the specific prior-art references and explain the bases for my opinions that those references disclose, or would have rendered obvious, the subject matter of the challenged claims.

VIII. THE '776 PATENT

A. Overview of the '776 Patent

64. The '776 patent claims a spray-dried powder of the type long known in the encapsulation art: dried particles in which an active ingredient (food, flavor, fragrance, medicament, or pigment) is encapsulated within a carrier. EX-1001, Abstract, 1:25–67.

65. The claims purport to provide a powder by reference to a particular quantitative metric—the weight percentage of a “principle molecular type” of the active ingredient—measured either (i) before and after drying of a slurry of the active ingredient, carrier, and liquid solvent (independent claim 1: final active ingredient within about 5% of the initial active ingredient) (measuring *retention*) or (ii) after aging of the resulting powder during any period of an elevated temperature up to about 1000 hours (independent claim 10: variation within about 5% during aging at about 95°F) (measuring *stability*). EX-1001, claims 1, 10. Dependent claims 2–5 and 11–15 specify that the principle molecular types are of a food, flavor, fragrance, or medicament; dependent claims 7–9 and 16–18 narrow the retention or stability tolerance to about 3%, 2%, and 1%, respectively; and dependent claim 19 specifies that the carrier comprises starch. EX-1001, claims 1–19.

B. Prosecution History of the '776 Patent

66. The '776 patent issued on May 10, 2016, from U.S. Application No. 14/606,771 (filed January 27, 2015). See EX-1001.

67. This is a continuation-in-part of U.S. Application Ser. No. 13/245,369 (filed September 26, 2011), which claims the benefit of U.S. Provisional Patent Application No. 61/386,762 (filed September 27, 2010). See EX-1001, 1:7-21.

68. The application was rejected once on the merits. In a Non-Final Rejection dated February 17, 2016, the Examiner rejected claims 1-20 on

obviousness-type double patenting and claims 1-9 on prior-art grounds (single reference, Jennings (EX-1015), relating to a clay and cat litter mixture for cleaning concrete). EX-1002 (Non-Final Rejection, February 17, 2016).

69. In response, Applicant overcame the Jennings-based rejection via a Response, and concurrently filed a Terminal Disclaimer over commonly-owned U.S. Patent No. 8,939,388. EX-1002, 30-38 (Response, March 11, 2016; Terminal Disclaimer, March 11, 2016). In the Response, Applicant argued that Jennings “describes a two-component concrete cleaning mixture” that “lacks disclosure of any ‘spray dried powder,’” “does not ...mention ...‘encapsulation,’” and whose cited “ratio of 50% to 50%...is simply the ratio of the Kaolin...to the clay dust...with both being present at the same time with one another”—thus allegedly failing to show a powder whose principle molecular type is “essentially unchanged in weight from its raw ingredient state (being within about 5% of its weight percentage...prior to spray drying)”. EX-1002 (Response, March 11, 2016), 30-38. The Examiner thereafter issued a Notice of Allowance on March 31, 2016, and the patent issued on May 10, 2016. EX-1002 (Notice of Allowance, March 31, 2016; Issue Notification, Apr. 20, 2016).

70. As shown in the Grounds below, the prior art relied on in this proceeding discloses spray-dried powders meeting the claimed features, including the specific quantitative retention and stability thresholds recited in claims 1 and 10.

As to Subramaniam (EX-1004), the Examiner's filed References Considered lists Subramaniam among the cited references. EX-1002 (References Considered, Feb. 17, 2016, at No. 45). However, the Examiner only substantively considered Jennings during prosecution; the Examiner did not substantively consider Subramaniam. As to Baranauskiene (EX-1005) and Watanabe (EX-1006), the Examiner did not consider these references during prosecution, nor were these cited during prosecution of the '776 patent application.

IX. OVERVIEW AND COMBINATIONS OF PRIOR ART REFERENCES

A. Baranauskiene (EX-1005)

71. Baranauskiene (EX-1005) evaluates the effect of different commercial modified food starch carriers on the flavor retention of peppermint essential oil during spray drying. EX-1005, [3027] (Abstract), [3028]. Specifically, Baranauskiene evaluated these effects on eleven constituent components of peppermint essential oil ("EO"). The EO was emulsified into aqueous solutions of eight commercial starch carriers, creating eight different emulsions that were then spray dried. EX-1005, [3028]. This resulted in eight spray-dried powders in which the EO was encapsulated by eight different carriers, as shown in Table 2 (below, annotated). EX-1005, [3029], Table 1; [3031], Table 2.

Baranauskiene (EX-1005), Table 2

(annotated)

Boxes 1-8 = the eight commercial modified starch carriers

11 constituent
components
of peppermint
EO ('EO')

(same 11
components)

Table 2. Changes in the Total Oil Composition after Processing in Both Liquid-Emulsified and Spray-Dried Encapsulated Products as Compared with Pure Initial EO^a

no.	compound	KI on DB5	pure EO	1 HI-CAP 100		2 N-LOK		3 CAPSUL	
				emulsion	powder	emulsion	powder	emulsion	powder
1	limonene ^{c,e}	1032	0.6 bc	0.5 a	0.5 abc	0.5 a	0.4 a	0.5 abc	0.5 abc
2	menthone ^{c,e}	1166	19.5 cde	18.8 abc	19.0 bcde	19.0 bcde	18.8 abc	19.3 bcde	19.3 bcde
3	iso-menthone ^d	1176	16.0 bc	15.8 abc	16.0 bc	15.8 abc	15.3 a	16.4 c	15.8 abc
4	menthol ^{c,e}	1194	47.5 a	49.5 cde	49.1 bcde	49.3 bcde	50.0 de	48.5 bc	48.5 bc
5	iso-menthof ^{c,e}	1197	0.8 abc	0.9 bcde	0.9 abcde	0.9 abcde	0.7 a	1.0 cde	0.9 abcde
6	α-terpineol ^{c,e}	1201	0.9 c	0.8 b	0.8 b	0.8 b	0.9 cd	0.8 b	0.9 cd
7	cis-carveol ^d	1241	0.8 a	0.8 a	0.8 a	0.8 a	0.8 a	0.8 a	0.8 a
8	pulegone ^{c,e}	1249	2.2 e	1.9 a	2.1 d	2.1 bcd	2.1 d	2.1 cd	2.1 d
9	pipertone ^d	1264	1.5 g	1.0 a	1.3 de	1.2 bc	1.3 cd	1.2 bc	1.4 f
10	menthyl acetate ^{c,e}	1300	4.3 ab	4.3 ab	4.3 ab	4.3 ab	4.3 ab	4.3 ab	4.2 a
11	β-caryophyllene ^{c,e}	1433	1.3 ab	1.0 a	1.5 abcd	1.3 ab	1.0 a	1.0 a	1.5 abcd
	% RSD ^f		3.2	2.4	4.5	5.5	2.4	2.4	2.7

no.	4 ENCAPSUL 855		5 CRYSTAL TEX627		6 ClEmCap 12633		7 ClEmCap 12634		8 ClEmCap 12635	
	emulsion	powder	emulsion	powder	emulsion	powder	emulsion	powder	emulsion	powder
1	0.5 abc	0.4 a	0.5 abc	0.5 abc	0.5 a	0.6 bc	0.5 abc	0.6 bc	0.5 abc	0.6 c
2	19.8 cde	18.5 ab	18.1 a	18.8 abc	18.5 ab	20.0 e	18.8 abc	19.3 bcde	19.0 bcde	19.5 cde
3	16.1 bc	15.8 abc	15.8 abc	16.2 bc	15.5 abc	16.1 bc	16.2 bc	15.8 abc	16.0 bc	15.3 a
4	48.3 ab	50.0 e	49.1 bcde	49.0 bcde	50.1 de	48.3 ab	49.0 bcde	49.3 bcde	49.0 bcde	49.5 cde
5	0.8abc	0.9 bcde	1.1 e	0.8 abc	0.8 ab	0.8 ab	0.9 bcde	0.80 abc	0.8 abc	0.8 abc
6	0.8 b	0.9 cd	0.8 b	0.9 cd	0.8 b	0.8 b	0.8 b	0.8 b	0.8 b	0.1 a
7	0.9 bc	0.8 abc	0.8 a	0.6 abc	0.8 a	0.9 bc	0.8 a	0.8 abc	0.8 a	0.9 c
8	2.1 d	2.0 bc	2.0 ab	2.1 d	2.0 bc	2.1 cd	2.1 cd	2.1 d	2.1 d	2.1 d
9	1.2 b	1.3 cd	1.2 bc	1.3 cd	1.2 cd	1.2 cd	1.2 bc	1.2 bc	1.2 bc	1.3 ef
10	4.3 abc	4.2 a	4.4 bc	4.2 a	4.3 ab	4.4 bc	4.3 abc	4.4 c	4.3 ab	4.3 ab
11	1.3 ab	1.0 a	2.0 d	1.0 a	1.8 bcd	1.3 ab	1.5 abcd	1.0 a	1.5 abcd	1.0 a
	1.9	3.6	2.5	3.0	4.4	2.3	1.2	2.0	1.3	2.4

 = "emulsion" column (pre-dried)
 = "powder" column (spray-dried, encapsulated)

Each carrier (boxes 1-8) has both an emulsion and a powder column; "pure EO" is the initial oil before processing.

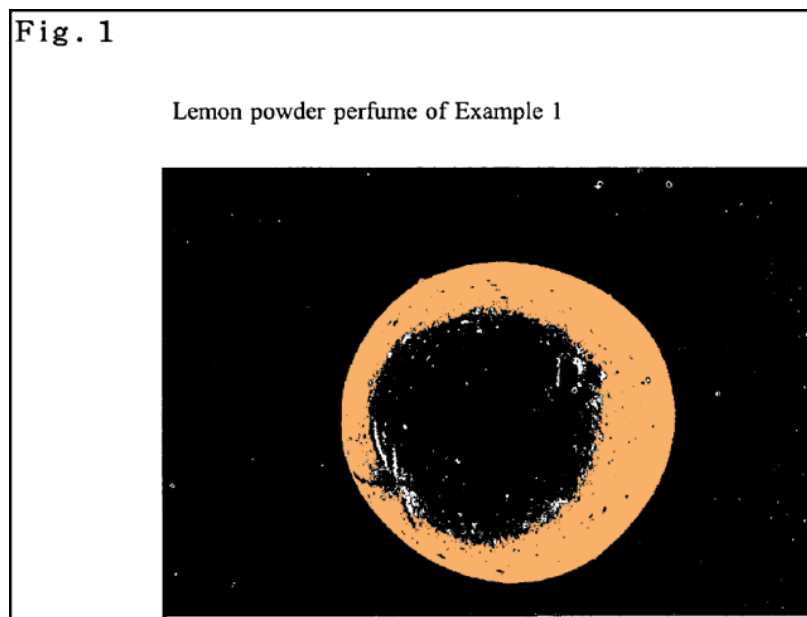
72. The compositions of the various EOs—pure starting EO (“pure EO”), EO recovered from each liquid emulsion (“emulsion”), and EO recovered from each spray-dried encapsulated powder (“powder”)—were determined for the eleven identified peppermint constituents, as reported in Table 2. EX-1005, [3028], [3031], Table 2. Baranauskiene reported that the peppermint EO composition (i.e., the eleven compounds) was essentially preserved through spray drying, confirming that the pure, emulsified, and encapsulated oils were “quite similar” across these eleven constituents, with only minor changes observed in a few individual compounds. EX-1005, [3027], [3031], Table 2; id. at 3027 (Abstract).

B. Watanabe (EX-1006)

73. Watanabe is directed to edible powder compositions comprising at least

one component selected from perfumes, coloring agents, and functional substances (e.g., vitamins), in combination with trehalose and water-soluble hemicellulose, prepared by spray drying an aqueous emulsion of those components. EX-1006, Abstract; [0001], [0006], [0008]–[0009], [0019]. Watanabe teaches that the resulting spray-dried powders “exhibit excellent shelf stability of the active component contained therein” and can be incorporated into drinks, foods, cosmetics, and the like to “impart a desired fragrance, flavor, color and/or function stably thereto for a long period of time.” EX-1006, [0001], [0006].

74. As Watanabe explains, the spray-dried particles take the form of “dense spherules having a stiff wall surface” and this morphology produces excellent stability of the active component contained therein. EX-1006, [0044], FIG. 1. Watanabe’s FIG. 1 (reproduced below; annotated) shows a scanning electron micrograph of a particle of Example 1’s spray-dried lemon powder perfume, highlighting this lemon powder perfume’s dense-spherule, stiff-walled morphology. EX-1006, Fig. 1. The orange annotation highlights the continuous, intact carrier wall enclosing the particle interior—the “dense spherule having a stiff wall surface” that Watanabe credits with the excellent stability of the perfume contained therein. EX-1006, [0043]–[0044], FIG. 1. This figure thus highlights that the active ingredient is encapsulated within the carrier.



75. Watanabe further explains that the same emulsion-and-spray-drying process used to prepare the lemon powder perfume is also used to prepare Example 5's paprika-containing powder. EX-1006, [0023], [0053]. In Example 5, water-soluble hemicellulose and trehalose were dissolved in water, paprika oil was emulsified into the solution, and the emulsion was spray-dried using a Mobile Minor type spray dryer (Niro Inc.) to yield a paprika-containing powder (which Watanabe references as "inventive product 5"). EX-1006, [0053].

76. Watanabe further teaches that, after storage at 50°C for 4 weeks (672 hours) in a low-density polyethylene bag in the dark, the inventive product 5 powder retained 97.5% of its "paprika pigment," as measured by spectrophotometry against the content of paprika pigment immediately after preparation (=100%). EX-1006, [0055]–[0058], Table 3 (reproduced below).

TABLE 3

Retention of Paprika Pigment	
After storage at 50° C. for 4 weeks	
Example 5	97.5%
Comparative Example 5	32.8%

C. The JECFA References (EX-1033, EX-1034)

77. The JECFA References are two companion documents on paprika extract issued by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in connection with its 69th meeting (2008): the JECFA specification monograph for paprika extract (“JECFA Monograph,” EX-1033), and the paprika-extract Chemical and Technical Assessment prepared as background documentation for that same meeting (“JECFA CTA,” EX-1034). EX-1033, 51²; EX-1034, 1. Together they describe paprika color’s composition and measurement. The JECFA Monograph discloses that paprika extract derives its color from a mixture of carotenoids in which capsanthin and capsorubin are the principal red compounds (not less than 30% of total carotenoids), and that this color is quantified as a single bulk total-carotenoid value by visible spectrophotometry at about 462 nm, expressed in capsanthin (capsanthin/capsorubin) equivalents. EX-1033, 51–52, 54–56. The JECFA CTA supplies corresponding compositional detail, reporting a representative

² EX-1033 citations reference page number at the top of the page.

carotenoid profile and confirming that capsanthin is the predominant carotenoid, contributing up to 60% of total carotenoids. EX-1034, 3–4. The JECFA References thus establish that a POSITA understood paprika’s “paprika pigment” to be a carotenoid mixture dominated by capsanthin and measured in bulk as capsanthin equivalents.

D. Subramaniam (EX-1004)

78. Subramaniam, titled “Spray-Drying Compositions and Method for their Preparation,” is directed to “compositions in an encapsulated form and to a method for the preparation of said compositions.” EX-1004, [0001]. Subramaniam teaches that “[s]pray-drying is a well-known useful technique to stabilize flavors by encapsulating them in a solid form” and that, in spray-dried powders, the active ingredient is “entrapped as liquid droplets in a solidified matrix of a dehydrated carrier, generally consisting of carbohydrates, such as starches, hydrolyzed starches (maltodextrin), chemically modified starches, emulsifying polymers (gum arabic)....” EX-1004, [0004]–[0005].

79. Subramaniam focuses on using agar agar in the carrier matrix, in combination with a wall-forming carbohydrate, to encapsulate the active ingredient. EX-1004, [0009]–[0013], [0020]–[0022]. Subramaniam further teaches that its spray-dried compositions exhibit “particularly advantageous stability in a medium of high relative humidity.” EX-1004, [0022].

80. The active ingredient of Subramaniam's spray-dried composition is broadly described as "a liquid ingredient, preferably hydrophobic, which is sought to be protected by way of solid encapsulation," and "may include volatile perfuming or flavoring ingredients, as well as other kinds of ingredients such as pharmaceutical actives." EX-1004, [0015].

81. Subramaniam's preparation method (set in Example 1, and used in Examples 2-7), prepares an aqueous emulsion of the carrier and active ingredient and spray-dries the homogenized feed. EX-1004, [0050]–[0051], [0064].

82. Subramaniam reports seven examples, the first five of which measure active ingredients' *retention* in spray-dried powders after the spray-drying process. Examples 1-4 prepare spray-dried compositions containing lemon oil (40-50% dry weight) in a maltodextrin/sucrose/agar agar carrier and report flavor retention values of 85% to 87.8% after the spray-drying process. EX-1004, [0049]–[0059]. Example 5 prepares a spray-dried composition containing fragrance at 30% dry weight in the same carrier system, and reports retention of 100% after spray-drying. EX-1004, [0060]–[0061]. Example 6 prepares a spray-dried composition containing orange oil, which is then further extruded to yield a glassy matrix. EX-1004, [0062]–[0063].

83. Unlike Examples 1–5, Example 7 measures active ingredients' *stability* in the spray-dried powder after it is exposed to an aging/storage test. Specifically, Example 7 presents a comparative stability example: two spray-dried

compositions—Formulation A (with 3% agar agar) and Formulation B (without agar agar)—are prepared, each containing a five-component perfume composition (benzyl acetate, phenylethyl acetate, cyclamen aldehyde, Lilial®, and hexyl salicylate, each at equal weight percentage) encapsulated in a maltodextrin/sucrose carrier; the powders are admixed with a detergent containing a percarbonate-TAED bleaching system, stored at 37°C/70% relative humidity for four weeks, and the residual perfuming ingredients are quantified by GC-MS. EX-1004, [0064]–[0067], Table 1.

X. MANNER IN WHICH THE PRIOR ART REFERENCES RENDER THE '776 CLAIMS UNPATENTABLE

A. Ground 1: Baranauskiene Renders Obvious Claims 1-5 and 7-9

Independent Claim 1

84. In the analysis of Ground 1 below, I use bold italics to identify claimed features and underlined to show emphasis that I have added to the cited disclosures.

[1pre] A spray dried powder, comprising:

85. If the preamble is limiting, Baranauskiene discloses *a spray-dried powder*.

86. Baranauskiene's title is "Flavor Retention of Peppermint (*Mentha piperita* L.) Essential Oil Spray-Dried in Modified Starches during Encapsulation

and Storage.” EX-1005, [3027] (Title). Baranauskiene reports that its disclosed “[e]mulsions were spray-dried” in a Büchi 190 Mini Spray Dryer (Büchi Labortechnik AG, Flawil, Switzerland). EX-1005, [3028]. The resulting product is repeatedly described as a “spray-dried encapsulated powder” or “spray-dried powder.” See, e.g., EX-1005, [3028], [3031] (Table 2 caption: “Spray-Dried Encapsulated Products”).

87. Accordingly, Baranauskiene discloses *a spray-dried powder*.

[1a] a plurality of dried particles, which individually contain an amount of final active ingredient encapsulated within a carrier resulting from drying a slurry containing an initial active ingredient, a liquid solvent and the carrier, wherein:

88. Baranauskiene discloses *a plurality of dried particles* (e.g., the spray-dried encapsulated peppermint EO powder particles), *which individually contain an amount of final active ingredient* (e.g., the peppermint EO recovered from the powder) *encapsulated within a carrier* (e.g., the modified food starch matrix) *resulting from drying a slurry* (e.g., the spray-dried emulsion) *containing an initial active ingredient* (e.g., the pure peppermint EO emulsified into the matrix), *a liquid solvent* (e.g., deionized water), *and the carrier* (e.g., the modified food starch).

89. Baranauskiene describes the preparation of the spray-dried particles (*plurality of dried particles*) as follows: “The solutions of coating matrices (30%

w/w) were prepared by dispersing dried powders in 40 °C deionized water, and after they were cooled, they were mixed overnight to enhance hydration. EO (15.25% w/w of matrix solids) was emulsified into the hydrated coating material. Homogenization was accomplished by an Ultra Turrax Ika 25 basic homogenizer (Janke & Kunkel GmbH&Co, Germany) operating at 13500 rpm for 7 min. Emulsions were spray-dried in a Büchi 190 Mini Spray Dryer” EX-1005, [3028].

90. Baranauskiene’s peppermint essential oil (“EO”) is an *active ingredient* contained in the plurality of dried particles, consistent with how this term is used in the ’776 patent. The ’776 specification describes an active ingredient as “any desirable single constituent component or a combination of constituent components” imparting a desirable characteristic, such a flavor or fragrance, to an end product. EX-1001, 6:10–15; *see also id.*, 1:40–43, 4:30–34. Further, the ’776 patent treats flavor and fragrance oils as active ingredients. *See* EX-1001, 13:27–29; 14:48–50, Example 1, FIG. 11. Baranauskiene’s peppermint essential oil (“EO”) has several constituent components (described in detail in [1b], below) that contribute to peppermint flavor.

91. Baranauskiene discloses a *slurry* consistent with how that term is described in the ’776 specification. *See* EX-1001, 1:60-67 (“The process begins with making a slurry of ingredients. The ingredients include a liquid solvent, such as

water 1, a carrier 2, and active ingredient(s) 3. In the typical process, the water 1 and carrier 2 are added into the solution tank 4 while stirring. The active ingredient 3 is then added to the tank 4 and stirred into the slurry. The active ingredient is either emulsified in the carrier fluid system or dissolved into it.”). Similarly, Baranauskiene’s above-described emulsion is a *slurry* because it contains (i) peppermint EO (*initial active ingredient*), (ii) deionized water (*liquid solvent*), and (iii) the modified food starch (*carrier*).

92. Baranauskiene discloses that the spray-dried powder *results from drying* this *slurry*. EX-1005, [3028] (“Emulsions were spray-dried in a Büchi 190 Mini Spray Dryer . . .”). A POSITA would have understood that the spray-dried powder includes a plurality of dried particles.

93. Baranauskiene further discloses the *plurality of dried particles* each/*individually contain an amount of the final active ingredient* (peppermint EO) that is *encapsulated within* the modified-starch *carrier*. Baranauskiene refers to its spray-dried products as “microencapsulated peppermint EO products” and separately reports (as shown in Table 1 below, annotated) the total oil content (the encapsulated EO) and surface oil content (the non-encapsulated EO) for each product, confirming that EO is encapsulated within the carrier in each particle. EX-1005, [3027] (Abstract); [3028] (“modified food starch matrices were used as encapsulating agents”); [3029]-[3030], Table 1 (reporting “Total Oil, g/100g d.s.”

and “Surface Oil, g/100g d.s.” for each product).

Baranauskiene (EX-1005), Table 1 (annotated)

Boxes 1-8 = the eight commercial modified-starch carriers

Table 1. Properties of Liquid Emulsion and Spray-Dried Microencapsulated Peppermint EO Products

	1 HI-CAP 100	2 N-LOK	3 CAPSUL	4 ENCAPSUL 855	5 CRYSTAL TEX 627	6 CIEmCAP 12633	7 CIEmCAP 12634	8 CIEmCAP 12635
total oil content (g 100 g ⁻¹)	15.03 cd	14.44 bcd	14.73 bcd	13.54 a	14.14 ab	15.21 d	14.44 bcd	14.81 bcd
emulsification efficiency ^a (%)	98.56 cd	94.69 bcd	96.59 bcd	88.78 a	92.72 ab	99.74 d	94.69 bcd	97.11 bcd
liquid microencapsulated product								
total oil content (g 100 g ⁻¹)	13.49 b	12.15 e	13.96 c	6.10 a	9.41 d	14.94 g	13.67 bc	14.48 f
surface oil content (g 100 g ⁻¹)	0.20 cd	0.18 bc	0.25 def	0.13 ab	0.23 cdef	0.08 a	0.17 bc	0.29 f
encapsulation efficiency ^a (%)	87.15 b	78.49 e	89.90 c	39.15 a	60.19 d	97.44 g	88.52 bc	93.05 f
moisture (mL 100 g ⁻¹)	1.83 a	2.08 ab	3.34 cd	1.49 a	3.39 cd	2.35 ab	2.85 bcd	3.75 d
water activity (a _w)	0.39 ab	0.43 abc	0.35 a	0.45 bc	0.44 bc	0.44 bc	0.49 cde	0.55 e
particle size weighted mean diameter d ₃ (μm)	27.19 d	34.99 f	30.50 e	11.9 a	23.52 b	137.63 h	56.88 g	24.82 c
specific surface area (m ² g ⁻¹)	17.7 e	16.6 d	16.8 d	0.7 a	10.5 a	4.3 b	19.4 f	17.4 e

^a Computed on the basis of a theoretical oil content of 15.25% of the solids. For letters a-h, values within rows followed by the same letter do not differ statistically at $P = 0.05$.

□ = 8 modified-starch carriers (boxes 1-8) ■ = EMULSION: liquid product (pre-dried) ■ = ENCAPSULATED: spray-dried product

□ Each dried particle holds EO encapsulated in the starch carrier — Total oil = encapsulated EO • Surface oil = non-encapsulated EO

94. Accordingly, Baranauskiene discloses *a plurality of dried particles, which individually contain an amount of final active ingredient encapsulated within a carrier resulting from drying a slurry containing an initial active ingredient, a liquid solvent and the carrier.*

[1b] the initial active ingredient includes one or more constituent components, at least one of which is among one or more principle molecular types from which at least one of a desirable food, flavor, fragrance, medicament, and pigment is obtained;

95. Baranauskiene discloses *the initial active ingredient* (e.g., pure

peppermint EO) *includes one or more constituent components* (e.g., at least one of the eleven peppermint EO compounds in Table 2), *at least one of which is among one or more principle molecular types* (e.g., Menthol, menthone, iso-menthone + neo-menthol, menthyl acetate, and pulegone) *from which at least one of a desirable flavor* (e.g., peppermint flavor) *is obtained*.

96. The *initial active ingredient* in Baranauskiene—pure peppermint EO—is a complex mixture of 57 identified volatile compounds. EX-1005, [3031]. Table 2 (reproduced below) reports on eleven of these identified compounds in the pure peppermint EO. EX-1005, [3028]; [3031], Table 2. Each of these compounds is a *constituent component* of the pure peppermint oil.

Baranauskiene (EX-1005), Table 2
(annotated)
Boxes 1-8 = the eight commercial modified starch carriers

Table 2. Changes in the Total Oil Composition after Processing in Both Liquid-Emulsified and Spray-Dried Encapsulated Products as Compared with Pure Initial EO^a

no.	compound	KI on DB5	pure EO	1 HI-CAP 100		2 N-LOK		3 CAPSUL	
				emulsion	powder	emulsion	powder	emulsion	powder
1	limonene ^{c,e}	1032	0.6 bc	0.5 a	0.5 abc	0.5 a	0.4 a	0.5 abc	0.5 abc
2	menthone ^{c,e}	1166	19.5 cde	18.8 abc	19.0 bcde	19.0 bcde	18.8 abc	19.3 bcde	19.3 bcde
3	iso-menthone ^{b,d}	1176	16.0 bc	15.8 abc	16.0 bc	15.8 abc	15.3 a	16.4 c	15.8 abc
4	menthol ^{c,e}	1194	47.5 a	49.5 cde	49.1 bcde	49.3 bcde	50.0 de	48.5 bc	48.5 bc
5	iso-menthol ^{c,e}	1197	0.8 abc	0.9 bcde	0.9 abcde	0.9 abcde	0.7 a	1.0 cde	0.9 abcde
6	α-terpineol ^{c,e}	1201	0.9 c	0.8 b	0.8 b	0.8 b	0.9 cd	0.8 b	0.9 cd
7	cis-carveol ^d	1241	0.8 a	0.8 a	0.8 a	0.8 a	0.8 a	0.8 a	0.8 a
8	pulegone ^{c,e}	1249	2.2 e	1.9 a	2.1 d	2.1 bcd	2.1 d	2.1 cd	2.1 d
9	pipitone ^d	1264	1.5 g	1.0 a	1.3 de	1.2 bc	1.3 cd	1.2 bc	1.4 f
10	menthyl acetate ^{c,e}	1300	4.3 ab	4.3 ab	4.3 ab	4.3 ab	4.3 ab	4.3 ab	4.2 a
11	β-caryophyllene ^{c,e}	1433	1.3 ab	1.0 a	1.5 abcd	1.3 ab	1.0 a	1.0 a	1.5 abcd
	% RSD ^f		3.2	2.4	4.5	5.5	2.4	2.4	2.7

11 constituent components of peppermint EO ('EO')

no.	4 ENCAPSUL 855		5 CRYSTAL TEX627		6 CIEmCap 12633		7 CIEmCap 12634		8 CIEmCap 12635	
	emulsion	powder	emulsion	powder	emulsion	powder	emulsion	powder	emulsion	powder
1	0.5 abc	0.4 a	0.5 abc	0.5 abc	0.5 a	0.6 bc	0.5 abc	0.6 bc	0.5 abc	0.6 c
2	19.8 cde	18.5 ab	18.1 a	18.8 abc	18.5 ab	20.0 e	18.8 abc	19.3 bcde	19.0 bcde	19.5 cde
3	16.1 bc	15.8 abc	15.8 abc	16.2 bc	15.5 abc	16.1 bc	16.2 bc	15.8 abc	16.0 bc	15.3 a
4	48.3 ab	50.0 e	49.1 bcde	49.0 bcde	50.1 de	48.3 ab	49.0 bcde	49.3 bcde	49.0 bcde	49.5 abc
5	0.8abc	0.9 bcde	1.1 e	0.8 abc	0.8 ab	0.8 ab	0.9 bcde	0.80 abc	0.8 abc	0.8 abc
6	0.8 b	0.9 cd	0.8 b	0.9 cd	0.8 b	0.8 b	0.8 b	0.8 b	0.8 b	0.1 a
7	0.9 bc	0.8 abc	0.8 a	0.8 abc	0.8 a	0.9 bc	0.8 a	0.8 abc	0.8 a	0.9 c
8	2.1 d	2.0 bc	2.0 ab	2.1 d	2.0 bc	2.1 cd	2.1 cd	2.1 d	2.1 d	2.1 d
9	1.2 b	1.3 cd	1.2 bc	1.3 cd	1.2 cd	1.2 cd	1.2 bc	1.2 bc	1.2 bc	1.3 ef
10	4.3 abc	4.2 a	4.4 bc	4.2 a	4.3 ab	4.4 bc	4.3 abc	4.4 c	4.3 ab	4.3 ab
11	1.3 ab	1.0 a	2.0 d	1.0 a	1.8 bcd	1.3 ab	1.5 abcd	1.0 a	1.5 abcd	1.0 a
	1.9	3.6	2.5	3.0	4.4	2.3	1.2	2.0	1.3	2.4

(same 11 components)

Legend: emulsion = "emulsion" column (pre-dried) powder = "powder" column (spray-dried, encapsulated) pure EO = "pure EO" column (initial oil)

Each carrier (boxes 1-8) has both an emulsion and a powder column; "pure EO" is the initial oil before processing.

97. Baranauskiene discloses that the initial active ingredient includes *one*

or more principle molecular types from which at least one of a desirable food, flavor, fragrance, medicament, and pigment is obtained. In the context of the '776 patent, a “principle molecular type” from which a desirable characteristic (here, flavor) of the active ingredient is obtained encompasses a constituent component that contributes to the desired characteristic (here, flavor), such that when the component’s concentration decreases in the overall spray-dried composition, the desired characteristic (here, flavor) is likewise undesirably altered. EX-1001, 2:31–37. For example, the '776 patent identifies D-limonene as the “principle molecular type” of orange oil, describing D-limonene as “[t]he most abundant and readily perceived molecule in citrus flavors,” and further explaining that “[a] decrease of d-limonene concentration in the citrus flavor composition dramatically alters the citrus flavor in an undesirable manner.” EX-1001, 12:18–21, Fig. 11; 15:18–23; *see also* EX-1001, 2:18–30 (using “principle” and “principal” interchangeably: “[s]imilar results were found for all other principal constituents of other flavor oils”); EX-1001, 15:53–54 (describing “Gamma-terpinene” as “contribut[ing] to the top note of the flavor” in “lemon and lime oils”), 16:22–24 (describing terpineols as “a small constituent of citrus oils, which contribute to heavier, less fresh tastes”); EX-1002 (Applicant Arguments, Mar. 11, 2016, at 7) (characterizing the limitation as “a molecular type for obtaining a food, flavor, fragrance, medicament, and/or pigment”). Additionally, the claims’ recitation of “one or more”/“at least one of”

confirms a single active ingredient may have multiple principle molecular types and, thus, is not limited to a single most abundant/dominant constituent component of an active ingredient. EX-1001, claims 1 [1d], 10 [10c].

98. Consistent with these '776 patent disclosures, Baranauskiene discloses that at least one of the eleven identified constituent components (in Table 2) of the *initial active ingredient* (peppermint EO) is a *principle molecular type from which the desirable flavor* (peppermint flavor) is obtained. In particular, Baranauskiene identifies five constituent components of peppermint EO—“[m]enthol (47.5%), menthone (19.5%), iso-menthone + neo-menthol (1.1:1) (16.0%), menthyl acetate (4.3%), and pulegone (2.2%)”—as “the major compounds among 57 volatiles identified in pure peppermint EO used as the initial material for the encapsulation (Table 2).” EX-1005, [3031]. One or more of these five “major” constituent components are “flavor compounds” of the EO that contribute to its desirable flavor. EX-1005, [3027], [3031], [3033]. The claim’s “one or more”/“at least one of” language confirms that the peppermint EO may have multiple principle molecular types and is not limited to the single most abundant/dominant constituent. EX-1001, 17:66–18:1, 18:8 (claim 1); *id.* at 18:47–52 (claim 10), 20:7–21 (claim 20), 18:19–21 (claim 4), 18:63–65 (claim 13). Nevertheless, even if abundance of the constituent component is relevant for purposes of the present limitation, Baranauskiene confirms that one or more of these “major” compounds (e.g.,

menthone, menthol) are relatively more abundant in peppermint EO. EX-1005, [3031].

99. Accordingly, Baranauskiene discloses *the initial active ingredient includes one or more constituent components, at least one of which is among one or more principle molecular types from which at least one of a desirable food, flavor, fragrance, medicament, and pigment is obtained.*

[1c] the final active ingredient includes one or more of the constituent components corresponding with those of the initial active ingredient as modified by the drying of the slurry; and

100. Baranauskiene discloses that *the final active ingredient* (e.g., the peppermint EO recovered from the spray-dried encapsulated powder) *includes one or more of the constituent components* (e.g., the eleven components in Table 2 for each spray-dried product) *corresponding with those of the initial active ingredient* (e.g., the same eleven components of the pure peppermint EO) *as modified by the drying of the slurry.*

101. Baranauskiene discloses *the final active ingredient* as the peppermint EO encapsulated in the spray-dried powder. As explained in [1a], the peppermint EO that is the *initial active ingredient* is emulsified in aqueous modified-starch carrier solutions and then spray dried to obtain dry powders in which the peppermint

EO is encapsulated within the starch matrix. EX-1005, [3031], Table 2 (reporting the composition of each emulsion and the resulting spray-dried powder). Baranauskiene confirms that this encapsulated EO is recovered from the finished powders, reporting that the “volatiles from liquid-emulsified and spray-dried encapsulated products were isolated by hydrodistillation and analyzed by GC and GC-MS.” EX-1005, [3031].

102. The peppermint EO recovered from the spray-dried powder ***includes one or more of the constituent components corresponding with those of the initial active ingredient***. Baranauskiene identifies, in the recovered EO of the encapsulated powders, the same constituent compounds that were present in the pure peppermint EO used as the starting material—reporting their peak-area percentages side by side. EX-1005, [3030]–[3031], Table 2. As shown below, the eleven constituents tabulated for the pure EO are each present in every spray-dried encapsulated powder, including each of the major constituents of the initial EO: menthol, menthone, isomenthone + neo-menthol, menthyl acetate, and pulegone. *Id.* Each constituent component of the recovered EO thus corresponds to a constituent component of the initial pure EO. EX-1005, [3031], Table 2.

Baranauskiene (EX-1005), Table 2

(annotated)

Boxes 1-8 = the eight commercial modified starch carriers

11 constituent components of peppermint EO ('EO')

(same 11 components)

Table 2. Changes in the Total Oil Composition after Processing in Both Liquid-Emulsified and Spray-Dried Encapsulated Products as Compared with Pure Initial EO^a

no.	compound	KI on DB5	pure EO	1 HI-CAP 100		2 N-LOK		3 CAPSUL	
				emulsion	powder	emulsion	powder	emulsion	powder
1	limonene ^{c,e}	1032	0.6 bc	0.5 a	0.5 abc	0.5 a	0.4 a	0.5 abc	0.5 abc
2	menthone ^{c,e}	1166	19.5 cde	18.8 abc	19.0 bcde	19.0 bcde	18.8 abc	19.3 bcde	19.3 bcde
3	iso-menthone ^{b,d}	1176	16.0 bc	15.8 abc	16.0 bc	15.8 abc	15.3 a	16.4 c	15.8 abc
4	menthol ^{c,e}	1194	47.5 a	49.5 cde	49.1 bcde	49.3 bcde	50.0 de	48.5 bc	48.5 bc
5	iso-menthol ^{c,e}	1197	0.8 abc	0.9 bcde	0.9 abcde	0.9 abcde	0.7 a	1.0 cde	0.9 abcde
6	α-terpineol ^{c,e}	1201	0.9 c	0.8 b	0.8 b	0.8 b	0.9 cd	0.8 b	0.9 cd
7	cis-carveol ^d	1241	0.8 a	0.8 a	0.8 a	0.8 a	0.8 a	0.8 a	0.8 a
8	pulegone ^{c,e}	1249	2.2 e	1.9 a	2.1 d	2.1 bcd	2.1 d	2.1 cd	2.1 d
9	pipitone ^d	1264	1.5 g	1.0 a	1.3 de	1.2 bc	1.3 cd	1.2 bc	1.4 f
10	menthyl acetate ^{c,e}	1300	4.3 ab	4.3 ab	4.3 ab	4.3 ab	4.3 ab	4.3 ab	4.2 a
11	β-caryophyllene ^{c,e}	1433	1.3 ab	1.0 a	1.5 abcd	1.3 ab	1.0 a	1.0 a	1.5 abcd
	% RSD ^f		3.2	2.4	4.5	5.5	2.4	2.4	2.7

no.	4 ENCAPSUL 855		5 CRYSTAL TEX627		6 CIEmCap 12633		7 CIEmCap 12634		8 CIEmCap 12635	
	emulsion	powder	emulsion	powder	emulsion	powder	emulsion	powder	emulsion	powder
1	0.5 abc	0.4 a	0.5 abc	0.5 abc	0.5 a	0.6 bc	0.5 abc	0.6 bc	0.5 abc	0.6 c
2	19.8 cde	18.5 ab	18.1 a	18.8 abc	18.5 ab	20.0 e	18.8 abc	19.3 bcde	19.0 bcde	19.5 cde
3	16.1 bc	15.8 abc	15.8 abc	16.2 bc	15.5 abc	16.1 bc	16.2 bc	15.8 abc	16.0 bc	15.3 a
4	48.3 ab	50.0 e	49.1 bcde	49.0 bcde	50.1 de	48.3 ab	49.0 bcde	49.3 bcde	49.0 bcde	49.5 cde
5	0.8 abc	0.9 bcde	1.1 e	0.8 abc	0.8 ab	0.8 ab	0.9 bcde	0.80 abc	0.8 abc	0.8 abc
6	0.8 b	0.9 cd	0.8 b	0.9 cd	0.8 b	0.8 b	0.8 b	0.8 b	0.8 b	0.1 a
7	0.9 bc	0.8 abc	0.8 a	0.8 abc	0.8 a	0.9 bc	0.8 a	0.8 abc	0.8 a	0.9 c
8	2.1 d	2.0 bc	2.0 ab	2.1 d	2.0 bc	2.1 cd	2.1 cd	2.1 d	2.1 d	2.1 d
9	1.2 b	1.3 cd	1.2 bc	1.3 cd	1.2 cd	1.2 cd	1.2 bc	1.2 bc	1.2 bc	1.3 ef
10	4.3 abc	4.2 a	4.4 bc	4.2 a	4.3 ab	4.4 bc	4.3 abc	4.4 c	4.3 ab	4.3 ab
11	1.3 ab	1.0 a	2.0 d	1.0 a	1.8 bcd	1.3 ab	1.5 abcd	1.0 a	1.5 abcd	1.0 a
	1.9	3.6	2.5	3.0	4.4	2.3	1.2	2.0	1.3	2.4

Legend: = "emulsion" column (pre-dried) = "powder" column (spray-dried, encapsulated) = "pure EO" column (initial oil)

Each carrier (boxes 1-8) has both an emulsion and a powder column; "pure EO" is the initial oil before processing.

103. Finally, the constituent components of the recovered EO are present *as modified by the drying of the slurry* consistent with the '776 specification. In the '776 specification, the modifications described result from drying the slurry during the spray-drying process itself: "The droplets[,] however, do become heated to a point at which considerable portions of desired constituents of the droplets (i.e., portions of the load) are undesirably modified, such as evaporated and/or oxidized. The undesirable modification to the load (load loss) leads to a reduction in flavor (in the case of food loads), a reduction in aroma (in the case of fragrances), etc." EX-1001, 2:31–37. The specification thus identifies modification as the result of the spray-drying process—not as a separate, quantified requirement that any particular modification be present in the final active ingredient. EX-1001, 1:30–46.

104. Similarly, in Baranauskiene, the initial active ingredient is modified by drying the slurry because it is subjected to spray drying and recovered from the resulting powder in encapsulated form. Additionally, or alternatively, the initial active ingredient is modified by drying the slurry because the percentages of its individual constituents shift slightly as a result of that drying.

105. Baranauskiene confirms that its spray drying both encapsulates and slightly alters the EO. Baranauskiene reports that the “changes in the composition of complex aroma mixtures during encapsulation, i.e., emulsification and especially spray drying, are unavoidable,” and that, although the “compositions of pure, emulsified, and encapsulated in different starches matrices peppermint EO were quite similar; however, some changes in the percentages of some individual compounds were observed (Table 2).” EX-1005, [3031]. Table 2 documents these drying-induced changes constituent by constituent. For example, in the CIEmCap 12635 spray-dried powder, menthol increased from 47.5% to 49.5%, iso-menthone + neo-menthol decreased from 16.0% to 15.3%, piperitone decreased from 1.5% to 1.3%, and β -caryophyllene decreased from 1.3% to 1.0%, as compared with the pure EO. *See id.* Baranauskiene separately reports that the volatile monoterpene β -pinene was reduced roughly two- to three-fold in the encapsulated powders. EX-1005, [3031]. The composition of the EO recovered from the spray-dried powder is therefore the composition of the initial pure EO *as modified by the drying of the*

slurry.

106. Accordingly, Baranauskiene discloses *the final active ingredient includes one or more of the constituent components corresponding with those of the initial active ingredient as modified by the drying of the slurry.*

[1d] a weight percentage of at least one of the one or more principle molecular types in the final active ingredient is within about 5% of a weight percentage of the corresponding principle molecular types in the initial active ingredient.

107. Baranauskiene discloses *a weight percentage of at least one of the one or more principle molecular types (e.g., menthone) in the final active ingredient (e.g., the peppermint EO recovered from Baranauskiene's spray-dried encapsulated powder) is within about 5% of a weight percentage of the corresponding principle molecular types in the initial active ingredient (e.g., the pure peppermint EO before emulsification and spray drying).*

108. As to *weight percentage*, Baranauskiene measured *the . . . principle molecular types* of both the pure peppermint EO and the recovered, spray-dried EO using gas chromatography. Table 2 reports the result for each constituent as a peak-area percentage.

Baranauskiene (EX-1005), Table 2

(annotated)

Boxes 1-8 = the eight commercial modified starch carriers

11 constituent
components
of peppermint
EO ('EO')

(same 11
components)

Table 2. Changes in the Total Oil Composition after Processing in Both Liquid-Emulsified and Spray-Dried Encapsulated Products as Compared with Pure Initial EO^a

no.	compound	KI on DB5	pure EO	1 HI-CAP 100		2 N-LOK		3 CAPSUL	
				emulsion	powder	emulsion	powder	emulsion	powder
1	limonene ^{c,e}	1032	0.6 bc	0.5 a	0.5 abc	0.5 a	0.4 a	0.5 abc	0.5 abc
2	menthone ^{c,e}	1166	19.5 cde	18.8 abc	19.0 bcde	19.0 bcde	18.8 abc	19.3 bcde	19.3 bcde
3	iso-menthone ^{b,d}	1176	16.0 bc	15.8 abc	16.0 bc	15.8 abc	15.3 a	16.4 c	15.8 abc
4	menthol ^{c,e}	1194	47.5 a	49.5 cde	49.1 bcde	49.3 bcde	50.0 de	48.5 bc	48.5 bc
5	iso-menthol ^{c,e}	1197	0.8 abc	0.9 bcde	0.9 abcde	0.9 abcde	0.7 a	1.0 cde	0.9 abcde
6	α-terpineol ^{c,e}	1201	0.9 c	0.8 b	0.8 b	0.8 b	0.9 cd	0.8 b	0.9 cd
7	cis-carveol ^d	1241	0.8 a	0.8 a	0.8 a	0.8 a	0.8 a	0.8 a	0.8 a
8	pulegone ^{c,e}	1249	2.2 e	1.9 a	2.1 d	2.1 bcd	2.1 d	2.1 cd	2.1 d
9	pipitone ^d	1264	1.5 g	1.0 a	1.3 de	1.2 bc	1.3 cd	1.2 bc	1.4 f
10	menthyl acetate ^{c,e}	1300	4.3 ab	4.3 ab	4.3 ab	4.3 ab	4.3 ab	4.3 ab	4.2 a
11	β-caryophyllene ^{c,e}	1433	1.3 ab	1.0 a	1.5 abcd	1.3 ab	1.0 a	1.0 a	1.5 abcd
	% RSD ^f		3.2	2.4	4.5	5.5	2.4	2.4	2.7

no.	4 ENCAPSUL 855		5 CRYSTAL TEX627		6 CIEmCap 12633		7 CIEmCap 12634		8 CIEmCap 12635	
	emulsion	powder	emulsion	powder	emulsion	powder	emulsion	powder	emulsion	powder
1	0.5 abc	0.4 a	0.5 abc	0.5 abc	0.5 a	0.6 bc	0.5 abc	0.6 bc	0.5 abc	0.6 c
2	19.8 cde	18.5 ab	18.1 a	18.8 abc	18.5 ab	20.0 e	18.8 abc	19.3 bcde	19.0 bcde	19.5 cde
3	16.1 bc	15.8 abc	15.8 abc	16.2 bc	15.5 abc	16.1 bc	16.2 bc	15.8 abc	16.0 bc	15.3 a
4	48.3 ab	50.0 e	49.1 bcde	49.0 bcde	50.1 de	48.3 ab	49.0 bcde	49.3 bcde	49.0 bcde	49.5 cde
5	0.8 abc	0.9 bcde	1.1 e	0.8 abc	0.8 ab	0.8 ab	0.9 bcde	0.80 abc	0.8 abc	0.8 abc
6	0.8 b	0.9 cd	0.8 b	0.9 cd	0.8 b	0.8 b	0.8 b	0.8 b	0.8 b	0.1 a
7	0.9 bc	0.8 abc	0.8 a	0.8 abc	0.8 a	0.9 bc	0.8 a	0.8 abc	0.8 a	0.9 c
8	2.1 d	2.0 bc	2.0 ab	2.1 d	2.0 bc	2.1 cd	2.1 cd	2.1 d	2.1 d	2.1 d
9	1.2 b	1.3 cd	1.2 bc	1.3 cd	1.2 cd	1.2 cd	1.2 bc	1.2 bc	1.2 bc	1.3 ef
10	4.3 abc	4.2 a	4.4 bc	4.2 a	4.3 ab	4.4 bc	4.3 abc	4.4 c	4.3 ab	4.3 ab
11	1.3 ab	1.0 a	2.0 d	1.0 a	1.8 bcd	1.3 ab	1.5 abcd	1.0 a	1.5 abcd	1.0 a
	1.9	3.6	2.5	3.0	4.4	2.3	1.2	2.0	1.3	2.4

 = "emulsion" column (pre-dried)
 = "powder" column (spray-dried, encapsulated)
 = "pure EO" column (initial oil)

Each carrier (boxes 1-8) has both an emulsion and a powder column; "pure EO" is the initial oil before processing.

109. In a gas chromatograph, each oil constituent produces a separate signal, or *peak*, and that peak's size reflects how much of the constituent is present. Baranauskiene reports each constituent as its share of the combined area of all peaks. EX-1005, [3028] (constituents "expressed as a GC peak area percent"); [3031], Table 2. Table 2 reports these peak-area percentages for eleven identified constituents in the pure starting oil (*initial active ingredient*) and in the spray-dried encapsulated powder (*final active ingredient*) for each of eight starch carrier products. *Id.*

110. Although element [1d] is written in terms of *weight* percentage, a constituent's peak-area percentage reliably tracks the change in its weight percentage for [1d]'s contemplated comparison. Element [1d] compares the same

molecular type in the initial and final active ingredients, and Baranauskiene analyzed that compound by the same GC-FID method, on the same instrument, in both the pure initial oil and the spray-dried product. EX-1005, [3028]. Because the same compound is measured the same way in both samples, its detector response is common to the initial and final values and cancels when the two are compared—so the relationship between that compound’s peak area and its actual weight is the same before and after drying. Thus, in my opinion, a POSITA would have understood or found obvious that the change in a constituent’s peak-area percentage from the initial to the final oil tracks the change in its weight percentage, such that where a constituent’s peak-area percentage is unchanged before and after drying, the change in its weight percentage is correspondingly small.

111. Applying that comparison, Baranauskiene discloses that *a weight percentage of at least one of the principle molecular types* (menthone) *in the final active ingredient is within about 5% of the weight percentage of the corresponding principle molecular type in the initial active ingredient*. As explained above, the peppermint essential oil (“EO”) was emulsified into aqueous solutions of eight commercial starch carriers, and then each emulsion was spray dried. EX-1005, [3028]. Table 2 sets forth the compositions of the pure starting EO, of the EO recovered from each liquid emulsion, and of the EO recovered from each of the eight spray-dried encapsulated powders, specifically reporting the peak-area percentage

of the eleven constituent components. For menthone in the CIEmCap 12635 spray-dried product, Table 2 reports the same peak-area percentage—19.5%—in both the pure EO and the spray-dried powder. EX-1005, [3031], Table 2.

Baranauskiene (EX-1005), Table 2 (annotated)

Table 2. Changes in the Total Oil Composition after Processing in Both Liquid-Emulsified and Spray-Dried Encapsulated Products as Compared with Pure Initial EO^a

no.	compound	KI on DB5	pure EO	HI-CAP 100		N-LOK		CAPSUL	
				emulsion	powder	emulsion	powder	emulsion	powder
1	limonene ^{c,e}	1032	0.6 bc	0.5 a	0.5 abc	0.5 a	0.4 a	0.5 abc	0.5 abc
2	menthone ^{c,e}	1166	19.5 cde	18.8 abc	19.0 bcde	19.0 bcde	18.8 abc	19.3 bcde	19.3 bcde
3	/iso-menthone ^{b,d}	1176	16.0 bc	15.8 abc	16.0 bc	15.8 abc	15.3 a	16.4 c	15.8 abc
4	menthol ^{c,e}	1194	47.5 a	49.5 cde	49.1 bcde	49.3 bcde	50.0 de	48.5 bc	48.5 bc
5	/iso-menthol ^{c,e}	1197	0.8 abc	0.9 bcde	0.9 abcde	0.9 abcde	0.7 a	1.0 cde	0.9 abcde
6	α -terpineol ^{a,e}	1201	0.9 c	0.8 b	0.8 b	0.8 b	0.9 cd	0.8 b	0.9 cd
7	cis-carveol ^d	1241	0.8 a	0.8 a	0.8 a	0.8 a	0.8 a	0.8 a	0.8 a
8	pulegone ^{c,e}	1249	2.2 e	1.9 a	2.1 d	2.1 bcd	2.1 d	2.1 cd	2.1 d
9	piperitone ^d	1264	1.5 g	1.0 a	1.3 de	1.2 bc	1.3 cd	1.2 bc	1.4 f
10	menthyl acetate ^{c,e}	1300	4.3 ab	4.3 ab	4.3 ab	4.3 ab	4.3 ab	4.3 ab	4.2 a
11	β -caryophyllene ^{c,e}	1433	1.3 ab	1.0 a	1.5 abcd	1.3 ab	1.0 a	1.0 a	1.5 abcd
	% RSD ^f		3.2	2.4	4.5	5.5	2.4	2.4	2.7

no.	ENCAPSUL 855		CRYSTAL TEX627		CIEmCap 12633		CIEmCap 12634		CIEmCap 12635	
	emulsion	powder	emulsion	powder	emulsion	powder	emulsion	powder	emulsion	powder
1	0.5 abc	0.4 a	0.5 abc	0.5 abc	0.5 a	0.6 bc	0.5 abc	0.6 bc	0.5 abc	0.6 c
2	19.8 cde	18.5 ab	18.1 a	18.8 abc	18.5 ab	20.0 e	18.8 abc	19.3 bcde	19.0 bcde	19.5 cde
3	16.1 bc	15.8 abc	15.8 abc	16.2 bc	15.5 abc	16.1 bc	16.2 bc	15.8 abc	16.0 bc	15.3 a
4	48.3 ab	50.0 e	49.1 bcde	49.0 bcde	50.1 de	48.3 ab	49.0 bcde	49.3 bcde	49.0 bcde	49.5 cde
5	0.8abc	0.9 bcde	1.1 e	0.8 abc	0.8 ab	0.8 ab	0.9 bcde	0.80 abc	0.8 abc	0.8 abc
6	0.8 b	0.9 cd	0.8 b	0.9 cd	0.8 b	0.8 b	0.8 b	0.8 b	0.8 b	0.1 a
7	0.9 bc	0.8 abc	0.8 a	0.8 abc	0.8 a	0.9 bc	0.8 a	0.8 abc	0.8 a	0.9 c
8	2.1 d	2.0 bc	2.0 ab	2.1 d	2.0 bc	2.1 cd	2.1 cd	2.1 d	2.1 d	2.1 d
9	1.2 b	1.3 cd	1.2 bc	1.3 cd	1.2 cd	1.2 cd	1.2 bc	1.2 bc	1.2 bc	1.3 ef
10	4.3 abc	4.2 a	4.4 bc	4.2 a	4.3 ab	4.4 bc	4.3 abc	4.4 c	4.3 ab	4.3 ab
11	1.3 ab	1.0 a	2.0 d	1.0 a	1.8 bcd	1.3 ab	1.5 abcd	1.0 a	1.5 abcd	1.0 a
	1.9	3.6	2.5	3.0	4.4	2.3	1.2	2.0	1.3	2.4

 = no. 2 menthone
 = "pure EO" (initial oil)
 = "powder" (spray-dried, encapsulated)
 = starch carrier

112. Because menthone's peak-area percentage is unchanged, its weight percentage is likewise essentially unchanged for the reasons noted earlier in this limitation's analysis. Thus, the change in menthone's weight percentage from the initial to final oil is well under 1%, below the claimed "about 5%" tolerance.

113. The change in menthone's weight percentage can also be confirmed

quantitatively, on a true mass-fraction basis. A gas chromatograph equipped with a flame ionization detector (as used by Baranauskiene, EX-1005, [3028]) does not measure mass directly; the detector's signal for a given constituent reflects both the amount of that constituent reaching the detector and the compound's particular response per unit mass. For a constituent i in the oil, the normalized peak-area fraction a_i reported in Table 2 is related to that constituent's weight fraction w_i by $a_i = (RF_i \cdot w_i) / \sum_j (RF_j \cdot w_j)$, where RF_i is the compound's mass response factor. EX-1035, 334–35 (Scanlon & Willis).

114. Solving for the weight fraction and defining $m_i = 1/RF_i$ —which represents the mass associated with each unit of detector response and is estimated below as (MW/ECN)—gives $w_i = (a_i \cdot m_i) / \sum_j (a_j \cdot m_j)$.

115. Element [1d] compares the same constituent before and after spray drying; it does not require determining that constituent's absolute weight percentage. Writing $S = \sum_j (a_j \cdot m_j)$ for the normalization sum of each oil, the before-and-after weight-fraction ratio for menthone (or any other constituent) can be expressed as $w(\text{final}) / w(\text{initial}) = [a(\text{final}) / a(\text{initial})] \cdot k$, where $k = S(\text{initial}) / S(\text{final})$. The mass response factor of the constituent being evaluated cancels because it is the same compound measured by the same method in both samples. For menthone, the reported peak-area percentage is unchanged at 19.5% before and after spray drying, so $a(\text{final}) / a(\text{initial}) = 1$ and the ratio depends entirely on k , which reflects how

much the overall oil composition changed. Because Baranauskiene reports that the pure, emulsified, and encapsulated oils were “quite similar” (EX-1005, [3031]), k is expected to be close to 1. This is consistent with Baranauskiene’s own statistical analysis: the superscript letters in Table 2 denote significance groupings under Duncan’s multiple range test at $P = 0.05$, and menthone’s reported percentage in the CIEmCap 12635 powder is the same as in the pure EO (19.5%), with no statistically significant change indicated. EX-1005, [3031], Table 2.

116. The mass response factors can be estimated using the effective carbon number, or ECN. In general, each aliphatic carbon contributes about 1 to the detector response, each olefinic carbon about 0.95, a ketone carbonyl carbon approximately 0, and the carbon bearing a secondary alcohol receives a partial adjustment of approximately -0.75 . EX-1035, 336 (Table I). The detector response per unit mass is therefore proportional to (ECN/MW) , so the area-to-weight conversion factor is $m = MW/ECN$. This adjustment matters because oxygenated compounds such as menthol and menthone carry more mass per unit of detector response than hydrocarbon terpenes such as limonene and β -caryophyllene—which is why GC-FID peak-area percentages should not simply be treated as interchangeable with weight percentages for a multicomponent oil of this kind. The following table sets forth the estimated conversion factor m for the eleven constituents reported in Table 2:

Constituent	Formula	ECN	MW	m = MW/ECN
limonene	C ₁₀ H ₁₆	9.80	136.23	13.90
menthone	C ₁₀ H ₁₈ O	9.00	154.25	17.14
iso-menthone + neo-menthol (≈1.1:1)	C ₁₀ H ₁₈ O / C ₁₀ H ₂₀ O	9.12	155.2	17.02
menthol	C ₁₀ H ₂₀ O	9.25	156.27	16.89
iso-menthol	C ₁₀ H ₂₀ O	9.25	156.27	16.89
alpha-terpineol	C ₁₀ H ₁₈ O	9.65	154.25	15.98
cis-carveol	C ₁₀ H ₁₆ O	9.05	152.23	16.82
pulegone	C ₁₀ H ₁₆ O	8.90	152.23	17.11
piperitone	C ₁₀ H ₁₆ O	8.90	152.23	17.11
menthyl acetate	C ₁₂ H ₂₂ O ₂	11.00	198.30	18.03
beta-caryophyllene	C ₁₅ H ₂₄	14.80	204.36	13.81

ECN contributions per the calculation method of Scanlon & Willis (1985) (EX-1035); the menthone result below is insensitive to the exact alcohol and ester corrections because those constituents are essentially unchanged before and after drying.

117. Applying this conversion to the eleven constituents reported in Table 2—which together account for about 95 to 96% of the oil—the contribution of each constituent to the calculation is $a \cdot m$, and adding those contributions gives the normalization sum, S , for each oil, using the pure EO and the CIEmCap 12635 spray-dried powder as the illustrative comparison:

Constituent	EO area%	12635 area%	EO (a·m)	12635 (a·m)
limonene	0.6	0.6	8.34	8.34
menthone	19.5	19.5	334.21	334.21
iso-menthone + neo-menthol	16.0	15.3	272.28	260.37
menthol	47.5	49.5	802.44	836.23
iso-menthol	0.8	0.8	13.51	13.51
alpha-terpineol	0.9	0.8	14.39	12.79
cis-carveol	0.8	0.9	13.46	15.14
pulegone	2.2	2.1	37.63	35.92
piperitone	1.5	1.3	25.66	22.24
menthyl acetate	4.3	4.3	77.52	77.52
beta-caryophyllene	1.3	1.0	17.95	13.81
TOTAL (S)	95.4	96.1	1617.4	1630.1

118. Using these totals, $k = S(\text{initial}) / S(\text{final}) = 1617.4 / 1630.1 = 0.9922$.

Because menthone has the same reported area percentage before and after spray drying (19.5% in both), its weight-fraction ratio is simply k —a relative difference of only about -0.78% . Expressed as weight percentages of the identified constituents, menthone is approximately 20.66 wt% in the pure essential oil and 20.50 wt% in the 12635 oil—i.e., the weight percentage is slightly higher than the reported area percentage because menthone is an oxygenated compound and produces somewhat less FID response per unit mass than the oil mixture as a whole:

Basis	Pure EO	12635	Abs. Δ	Rel. Δ
Area% (Table 2)	19.5	19.5	0.0 pt	0.0%
Weight% (ECN bridge)	20.66	20.50	-0.16 pt	-0.78%

119. This -0.78% figure is a deliberately conservative estimate. It accounts only for the constituents listed in Table 2 and does not credit the loss of minor volatile components—such as β -pinene, which Baranauskiene reports was reduced roughly two- to three-fold during drying (EX-1005, [3031]) and which is a relatively low-response hydrocarbon. Accounting for the loss of those components, or simply renormalizing the identified constituents, moves the calculated menthone difference closer to zero, to approximately -0.1% to -0.2% . The -0.78% value can therefore reasonably be regarded as an upper bound on the magnitude of the change in menthone's weight percentage.

120. The comparison is, if anything, further conservative because Table 2

reports the composition of the total recovered oil, whereas the claimed final active ingredient is more appropriately associated with the oil encapsulated inside the spray-dried particles. Baranauskiene reports that the surface (non-encapsulated) oil is only about 2.0% of the total oil in the CIEmCap 12635 product—0.29 g of surface oil out of 14.48 g of total oil per 100 g of powder. EX-1005, [3029]-[3030], Table 1. That surface oil is comparatively low in menthone—14.9%, versus 19.5% for the total oil. EX-1005, Table 3; [3031], Table 2. Removing the surface-oil contribution therefore raises the estimated menthone content of the encapsulated interior oil to about 19.6%, which is slightly higher than the value for the pure essential oil and makes the before-and-after match even closer.

121. In my opinion, this quantitative analysis confirms the conclusion stated above: the weight percentage of menthone (a principle molecular type) in the final active ingredient is within well under 1% of its weight percentage in the initial active ingredient—i.e., within [1d]’s “about 5%” tolerance.

122. Accordingly, Baranauskiene discloses *a weight percentage of at least one of the one or more principle molecular types in the final active ingredient is within about 5% of a weight percentage of the corresponding principle molecular types in the initial active ingredient*. EX-1005, [3031], Table 2.

Dependent Claim 2

[2] The spray dried powder of claim 1, wherein the one or more principle molecular types are molecular types of a food composition.

123. Baranauskiene discloses or renders obvious that *the one or more principle molecular types* (e.g., at least menthol, menthone, iso-menthone + neo-menthol, menthyl acetate, and pulegone of Baranauskiene’s peppermint EO, from which the flavor is obtained) are molecular types *of a food composition* (e.g., used for flavoring food compositions).

124. Baranauskiene teaches that “the encapsulation of flavor ingredients is among the most important applications in the food industry” (EX-1005, [3027]) and “[t]he controlled release of ingredients at the right place and the right time can improve the effectiveness of food additives...”). This interpretation is consistent with the ’776 patent, which contemplates that the same molecular type can be of a food or flavor composition, depending on end-use. EX-1001, 12:19–30, 15:18–24, 18:13–18, FIG. 11 (treating D-limonene of orange oil as simultaneously a flavor and a food principle molecular type). Given these disclosures, a POSITA would have thus understood that at least one of those constituents of Baranauskiene’s peppermint EO (i.e., *one or more principle molecular types*)—being a constituent from which peppermint flavor is obtained and which Baranauskiene teaches is encapsulated for flavoring food—is a *molecular type of a food composition*.

Dependent Claim 3

[3] The spray dried powder of claim 1, wherein the one or more principle molecular types are molecular types of a flavor composition.

125. Baranauskiene discloses or renders obvious that *the one or more principle molecular types* (e.g., at least menthol, menthone, iso-menthone + neo-menthol, menthyl acetate, and pulegone of Baranauskiene’s peppermint EO, from which the flavor is obtained) are molecular types *of a flavor composition* (e.g., used for flavoring food compositions).

126. Baranauskiene teaches that the purpose of its disclosed analysis was to test EO’s flavor retention. EX-1005, [3027] (Abstract: “The effect of different commercial modified food starch carrier materials on the flavor retention of the essential oil (EO) of peppermint . . . during spray drying and storage was evaluated.”). *Also* [3027] (“the encapsulation of flavor ingredients is among the most important applications in the food industry”); [3031] (“The changes in the composition of complex aroma mixtures during encapsulation, i.e., emulsification and especially spray drying, are unavoidable. The information on such changes is required to obtain high quality preparations with a specified flavoring”). A POSITA would have thus understood that at least one of Baranauskiene’s peppermint EO constituents (i.e., *one or more principle molecular types*)—being a constituent from

which peppermint flavor is obtained, and which Baranauskiene spray-dries and evaluates for flavor retention as a flavoring—is itself a *molecular type of a flavor composition*.

Dependent Claim 4

[4] The spray dried powder of claim 1, wherein the one or more principle molecular types are molecular types of a fragrance composition.

127. Baranauskiene discloses or renders obvious that *the one or more principle molecular types* (e.g., at least Menthol, menthone, iso-menthone + neo-menthol, menthyl acetate, and pulegone of Baranauskiene’s peppermint EO, from which fragrance is obtained) are molecular types *of a fragrance composition* (e.g., used for perfuming a product).

128. Baranauskiene describes the encapsulated EO in terms of its *aroma* properties—*i.e.*, its fragrance. EX-1005, [3027] (Abstract: “aroma binding capacity of different modified starch matrices to lock EO droplets”); [3031] (“The changes in the composition of complex aroma mixtures during encapsulation, *i.e.*, emulsification and especially spray drying, are unavoidable.”). A POSITA would have thus understood that at least one of Baranauskiene’s peppermint EO constituents (*i.e.*, *one or more principle molecular types*)—being a constituent from which the EO’s aroma, *i.e.*, its fragrance, is obtained—is itself a *molecular type of*

a fragrance composition.

Dependent Claim 5

[5] The spray dried powder of claim 1, wherein the one or more principle molecular types are molecular types of a medicament composition.

129. Baranauskiene discloses or renders obvious that *the one or more principle molecular types* (e.g., at least menthol, menthone, iso-menthone + neo-menthol, menthyl acetate, and pulegone of Baranauskiene's peppermint EO, from which therapeutic (pharmacological) activity is obtained) are molecular types *of a medicament composition* (e.g., used as/in a medicament).

130. In Baranauskiene, the active ingredient is peppermint EO. As of the priority date (September 2010), peppermint oil and some of its major components—specifically, menthone and menthol—were well-known as pharmacologically active and having established therapeutic uses. *See, e.g.*, EX-1016;³ EX-1017; EX-1020. A

³ Although EX-1016 displays a notation that it was superseded by a subsequent HMPC monograph adopted 15 January 2020, EX-1016 was the operative, HMPC-adopted Community herbal monograph on *Mentha x piperita* L., aetheroleum from its adoption on October 31, 2007, through January 2020, and therefore accurately reflects the state of the art as of the September 2010 priority date. EX-1016's

POSITA would have therefore understood that peppermint EO is a medicament composition, per the claim. Thus, one or more of the peppermint EO principle molecular types are *molecular types of a medicament composition*. EX-1005, [3031], Table 2.

Dependent Claim 7

[7] The spray dried powder of claim 1, wherein the weight percentage of at least one of the one or more principle molecular types in the final active ingredient is within about 3% of a weight percentage of the corresponding principle molecular types in the initial active ingredient.

131. Baranauskiene discloses claim 7 for the reasons explained above in [1d]. As explained above, menthone—one of Baranauskiene’s peppermint EO principle molecular types—is present at the same weight percentage in the spray-dried EO (*final active ingredient*) as in the pure EO (*initial active ingredient*), reflecting a change of well under 1%.

132. Accordingly, and as explained in [1d], a POSITA would have

teachings regarding peppermint oil’s (or menthone’s and menthol’s) known pharmacological activity and established therapeutic uses were not altered by the later revision.

understood that menthone's weight percentage (i.e., *the at least one of the one or more principle molecular types in the final active ingredient*) has well under 1% variance relative to the menthone in the initial EO before spray drying—and thereby, *is within about 3% of a weight percentage of the corresponding principle molecular types in the initial active ingredient.*

Dependent Claim 8

[8] The spray dried powder of claim 1, wherein the weight percentage of at least one of the one or more principle molecular types in the final active ingredient is within about 2% of a weight percentage of the corresponding principle molecular types in the initial active ingredient.

133. Baranauskiene discloses claim 8 for the reasons explained above in [1d]. As explained above, menthone—one of Baranauskiene's peppermint EO principle molecular types—is present at the same weight percentage in the spray-dried EO (*final active ingredient*) as in the pure EO (*initial active ingredient*), reflecting a change of well under 1%.

134. Accordingly, and as explained in [1d], a POSITA would have understood that menthone's weight percentage (i.e., *the at least one of the one or more principle molecular types in the final active ingredient*) has well under 1% variance relative to the menthone in the initial EO before spray drying—and thereby,

is within about 2% of a weight percentage of the corresponding principle molecular types in the initial active ingredient.

Dependent Claim 9

[9] The spray dried powder of claim 1, wherein the weight percentage of at least one of the one or more principle molecular types in the final active ingredient is within about 1% of a weight percentage of the corresponding principle molecular types in the initial active ingredient.

135. Baranauskiene discloses claim 9 for the reasons explained above in [1d]. As explained above, menthone—one of Baranauskiene’s peppermint EO principle molecular types—is present at the same weight percentage in the spray-dried EO (*final active ingredient*) as in the pure EO (*initial active ingredient*), reflecting a change of well under 1%.

136. Accordingly, and as explained in [1d], a POSITA would have understood that menthone’s weight percentage (i.e., *the at least one of the one or more principle molecular types in the final active ingredient*) has well under 1% variance relative to the menthone in the initial EO before spray drying—and thereby, *is within about 1% of a weight percentage of the corresponding principle molecular types in the initial active ingredient.*

**B. Ground 2: Watanabe in View of the JECFA References
Renders Obvious Claims 10-11, 15-17, and 19**

Watanabe–JECFA References Combination

137. I use three related — but not interchangeable — terms in the analysis that follows: “paprika extract” (JECFA’s term, EX-1033, 51), “paprika oil” (Watanabe’s term for Example 5’s active ingredient, EX-1006, [0053]), and “paprika pigment” (Watanabe’s term for the color attribute it measures and reports as retained, EX-1006, [0055]–[0056]). The first two name the same ingredient, and the third names that ingredient’s color-bearing fraction. EX-1033, 51; EX-1006, [0053], [0055]–[0056]. JECFA defines “paprika extract” as the solvent extract of *Capsicum annuum* fruit — a dark-red, oil-based (lipidic) liquid that may be standardized in refined vegetable oil. EX-1033, 51. In my opinion, Watanabe’s “paprika oil” is a commercial, oil-form example of that same paprika extract. EX-1006, [0053]; EX-1033, 51. The “paprika pigment” is that extract’s color-imparting fraction—the carotenoid mixture, principally capsanthin and capsorubin (EX-1033, 51; EX-1034, 3–4), that Watanabe measures spectrophotometrically and reports as retained (EX-1006, [0055]–[0056])—of which capsanthin is the predominant carotenoid. EX-1034, 3–4.

138. A POSITA would have found it obvious to combine the teachings of Watanabe with those of the JECFA References. Watanabe prepares and measures a paprika-containing spray-dried powder and reports its stability in terms of retained

“paprika pigment” measured spectrophotometrically, describing the pigment only in the aggregate. EX-1006, [0053], [0055]–[0056]. While Watanabe does not expressly enumerate the pigment’s constituents, in my opinion a POSITA working with paprika-colored material would have consulted recognized compositional and analytical standards for paprika extract. A POSITA would have thus sought out an authoritative statement of paprika-extract composition and assay—as captured by the JECFA References—to identify the carotenoids that make up paprika color, their representative proportions, and the spectrophotometric, capsanthin-equivalents basis on which paprika color is quantified. EX-1033, 51–52, 54–56; EX-1034, 3–4.

139. Independent of the “776 claims, in my opinion a POSITA had ordinary, practical reasons to determine the carotenoid composition underlying a bulk paprika-color measurement. Paprika (*Capsicum annuum*) color was a widely used commercial colorant that the art characterized, specified, and traded on the basis of its carotenoid content, and its color strength and storage stability were understood to depend on which carotenoids were present and in what proportions. EX-1033, 51; EX-1034, 3–4. It was accordingly routine in the art to resolve paprika color into its individual carotenoid constituents by HPLC and to report their relative proportions — e.g., Deli (2001) identified 34 carotenoids in ripe red paprika, and Mínguez-Mosquera and Topuz likewise reported component-level carotenoid profiles. EX-1018; EX-1019; EX-1021; EX-1034, 3–4. In my opinion, a POSITA presented with

Watanabe’s single aggregate spectrophotometric “paprika pigment” value—which does not itself identify any constituent—would therefore have consulted the recognized compositional and analytical authority for paprika extract, the JECFA References, to identify the carotenoids that make up paprika color, their representative proportions, and the capsanthin-equivalents basis on which the measurement is expressed. EX-1006, [0055]–[0056]; EX-1033, 51–52, 54–56; EX-1034, 3–4.

140. In my opinion, a POSITA would have had a reasonable expectation of success in combining the teachings of Watanabe and the JECFA References for multiple reasons. First, Watanabe discloses “paprika pigment” and the JECFA References disclose the specific components of that pigment along with per-component measurements of that pigment—thus providing a component-level measurement breakdown relative to the overall measurement of the same ingredient provided by Watanabe. Second, the combination call for no modification of Watanabe; the JECFA References simply confirm the composition of the paprika pigment Watanabe already discloses and measures—establishing that capsanthin is a principle molecular type of Watanabe’s active ingredient and that Watanabe’s bulk retention figure reflects capsanthin’s behavior. EX-1006, [0053], [0055]–[0056]; EX-1033, 51–52; EX-1034, 3–4.

141. In more detail, and as to composition, the JECFA Monograph sets a

compositional specification—capsanthin and capsorubin together comprising at least 30% of total carotenoids. EX-1033, 51–52. In my opinion, a POSITA would have reasonably expected Watanabe’s commercial paprika oil to fall within that characterized range, such that capsanthin is a principal constituent of Watanabe’s active ingredient. And, as to the measurement, the spectrophotometric assay at about 462 nm is the standard method for paprika color, expressed as total carotenoids in capsanthin equivalents. EX-1034, 3–4; EX-1033, 52, 54–55. In my opinion, a POSITA would have understood and reasonably expected Watanabe’s spectrophotometric paprika-pigment figure to be that same total-carotenoid, capsanthin-equivalents measurement, such that the JECFA assay basis describes what Watanabe’s number captures.

142. In summary, Watanabe provides a spray-dried, stored paprika-pigment powder and a spectrophotometric figure showing that pigment was retained after storage, while the JECFA References disclose the ordinary knowledge of what that pigment is—a carotenoid mixture dominated by capsanthin—and of the capsanthin-equivalents basis on which the figure is measured. In my opinion and in combination, a POSITA would have found obvious that Watanabe’s retained “paprika pigment” is a capsanthin-dominated carotenoid pool measured by the standard assay, such that Watanabe’s retention figure reflects the behavior of capsanthin as its principal constituent.

Independent Claim 10

[10pre] A spray dried powder, comprising:

143. If the preamble is limiting, Watanabe-JECFA References discloses *a spray-dried powder* (e.g., inventive product 5's paprika-containing powder). EX-1006, [0009], [0019], [0053].

144. Watanabe provides a powder composition prepared by spray drying an aqueous emulsion containing trehalose, water-soluble hemicellulose, and at least one component selected from perfumes, coloring agents, and functional substances. EX-1006, [0008]–[0009], [0019]. In Example 5, the emulsion was spray-dried using a Mobile Minor type spray dryer (manufactured by Niro Inc.) to obtain 95 g of a paprika-containing powder. EX-1006, [0053]. Inventive product 5's paprika-containing powder is thus *a spray-dried powder*.

[10a] a plurality of dried particles, which individually contain an amount of active ingredient encapsulated within a carrier, wherein:

145. Watanabe-JECFA References renders obvious *a plurality of dried particles* (e.g., paprika containing powder's spray-dried spherules), *which individually contain an amount of active ingredient* (e.g., paprika oil) *encapsulated within a carrier* (e.g., trehalose/water-soluble hemicellulose matrix).

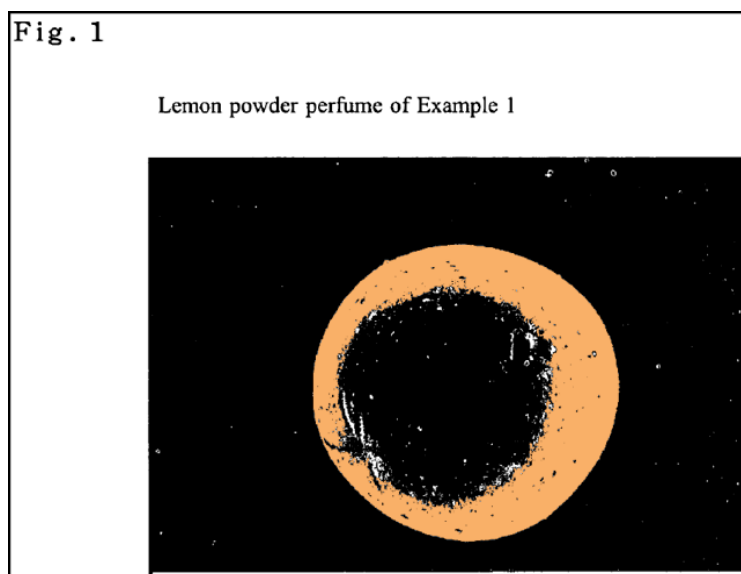
146. Watanabe’s spray-dried powder composition comprises trehalose, water-soluble hemicellulose, and at least one component selected from perfumes, coloring agents, and functional substances. EX-1006, [0008]–[0009], [0017].

147. In Example 5, paprika oil is the perfume/coloring agent component, and trehalose and water-soluble hemicellulose together form the *carrier* into which the paprika oil is incorporated (*encapsulated*) by emulsification and subsequently spray dried. EX-1006, [0053].

148. The paprika oil is the *active ingredient* per the ’776 patent’s description. The ’776 specification functionally describes an active ingredient as “any desirable single constituent component or a combination of constituent components, at least one of which is among one or more principle molecular types from which at least one of a desirable food, flavor, fragrance, medicament, pigment . . . is obtained.” EX-1001, 6:10–16. The patent thus contemplates a pigment-imparting component as an active ingredient, and dependent claim 15 confirms that the principle molecular types of an active ingredient may be those “of a pigment composition.” EX-1001, 19:4–6. Consistent with these descriptions, Watanabe’s paprika oil is an *active ingredient* at least because it is a coloring agent that imparts a desirable color—paprika pigment—to an end product, and it has several constituent components (carotenoid pigments described in [10b], below) from which that desirable pigment is obtained. EX-1006, [0011], [0053]. The

trehalose/water-soluble hemicellulose matrix is the *carrier*. EX-1006, [0008]-[0009], [0053].

149. Additionally, spray drying the emulsion yields a paprika powder composed of discrete particles (*a plurality of dried particles*). EX-1006, [0009], [0019], [0044]. Scanning electron micrographs at 2000× magnification show that the inventive product particles (Example 1, FIG. 1) form “dense spherules having a stiff wall surface,” and Watanabe teaches that this dense-spherule, stiff-walled morphology produces the contained active component’s excellent stability. EX-1006, [0044], FIG. 1. The same emulsion-and-spray-drying process used in Example 1 (trehalose/water-soluble hemicellulose carrier, Mobile Minor spray dryer, inlet 150–160°C, outlet 80°C) is used in Example 5 to produce the paprika-containing powder. EX-1006, [0023], [0053].



150. A POSITA would have understood that Example 5’s paprika-

containing powder has the same dense-spherule, stiff-walled morphology as Example 1 in FIG. 1, with the paprika oil held within each spherule's carrier shell. That is at least because Watanabe prepares Example 1's lemon-perfume powder and Example 5's paprika-containing powder by the same emulsion-and-spray-drying process, using the same trehalose/water-soluble hemicellulose carrier composition, the same Mobile Minor type spray dryer, and the same outlet temperature of 80°C. EX-1006, [0023], [0053]. Further, Watanabe attributes the dense-spherule, stiff-walled morphology in FIG. 1 to the carrier composition and spray-drying process—not to the active ingredient's identity—and identifies that morphology as the structural basis for the powder's excellent shelf stability of the active component contained therein. EX-1006, [0017], [0044]. Finally, Watanabe's Reference Example 3 reports that Example 5's paprika-containing powder exhibits the same excellent shelf stability of its active component (97.5% paprika-pigment retention after 4 weeks at 50°C) that Watanabe attributes to Example 1's dense-spherule, stiff-walled morphology. EX-1006, [0044], [0055]–[0058], Table 3.

151. Moreover, Watanabe's emulsion-and-spray-drying process is similar to the '776 patent's encapsulation mechanism. As the '776 patent explains, in spray drying “the slurry is fed into a drying chamber, usually a tower into which heated air is also introduced. The temperature of the air as it enters the drying chamber is well over the boiling point of water.... The heated air supplies energy for evaporation of

volatile components of the liquid (the water) from the droplets. As the water evaporates, the carrier forms a hardened shell around the load, producing a dried powder.” EX-1001, 1:45-57. Watanabe’s Example 5 process performs a similar encapsulation mechanism: the carrier components form a hardened shell around the paprika oil load as the water evaporates, producing a dried powder of encapsulated particles. EX-1006, [0053].

152. In summary, each *dried particle* of the Example 5 powder *contain[s] an amount of active ingredient* (paprika oil) *encapsulated within a carrier* (trehalose/water-soluble hemicellulose shell of the dense spherule). EX-1006, [0044], [0053], FIG. 1.

[10b] the active ingredient includes one or more constituent components, at least one of which is among one or more principle molecular types from which at least one of a desirable food, flavor, fragrance, medicament, and pigment is obtained; and

153. Watanabe-JECFA References render obvious that *the active ingredient* (e.g., paprika oil) *includes one or more constituent components at least one of which is among one or more principle molecular types* (e.g., capsanthin, paprika oil’s principal carotenoid constituent) *from which at least one of a desirable food, flavor, fragrance, medicament, and pigment is obtained* (e.g., paprika oil’s

desirable red pigment, obtained from capsanthin).

154. As explained at [10a], paprika oil is Example 5’s *active ingredient*. At least one desirable property that paprika oil contributes is its color, and Watanabe identifies that color property as the powder’s “paprika pigment”—the attribute whose retention is measured in Watanabe’s Reference Example 3 to evaluate the powder’s storage stability. EX-1006, [0053], [0055]–[0056], Table 3.

155. Although Watanabe does not itself enumerate the chemical constituents of its “paprika pigment,” it was well known and obvious to a POSITA that “paprika pigment” is a mixture of carotenoid constituents that together give paprika oil its characteristic red color—i.e., the constituent components of the active ingredient from which its pigment property is obtained. As set out above in the Watanabe–JECFA References Combination, a POSITA would have found it obvious to consult the JECFA References to determine the carotenoid composition of Watanabe’s paprika pigment, and would have done so with a reasonable expectation that those references accurately describe it. EX-1033, 51–52; EX-1034, 3–4. *See, e.g.*, EX-1018; EX-1019; EX-1034.

156. The JECFA References provide that composition. They disclose that paprika extract derives its color from a mixture of carotenoids in which capsanthin and capsorubin are the principal red, *Capsicum*-specific compounds (together not less than 30% of total carotenoids), and that capsanthin is the single predominant

carotenoid, contributing up to 60% of total carotenoids and the largest single share of paprika's red color. EX-1033, 51–52, 54–56; EX-1034, 3–4. The representative carotenoid profile of paprika extract, and capsanthin's dominant place within it, are detailed below in connection with [10c]. *See* EX-1018; EX-1019; EX-1034.

157. Among those carotenoid constituents, capsanthin is *the principle molecular type from which* paprika oil's desirable *pigment is obtained*: it is the *Capsicum*-specific red ketocarotenoid that is the single most abundant individual carotenoid in ripe red paprika and the largest single contributor to paprika's characteristic red color. EX-1033, 51–52; EX-1034, 3–4. *See, e.g.*, EX-1018; EX-1019. Capsanthin is therefore a *principle molecular type* within the meaning of [10b] at least because it is a principal, characteristic, and defining molecular constituent of paprika oil (active ingredient), and the molecule from which the desirable pigment (red color) of paprika oil is obtained. EX-1006, [0053], [0055]–[0056]. Watanabe confirms this in view of its teaching that its powder compositions are “incorporated into various drinks, foods, cosmetics and the like” to “impart a desired...color...stably thereto for a long period of time”—i.e., the capsanthin-derived red pigment is a desirable property of the active ingredient that the powder is designed to deliver, including in *food* products. EX-1006, [0001], [0006]. The JECFA References corroborate that color is paprika extract's defining, intended property. The JECFA Monograph classifies paprika extract as a food color additive

(INS No. 160c) and expressly lists its functional use as “Colour.” EX-1033, 51–52. The JECFA CTA likewise describes paprika extract’s extensive use in the food industry as a natural colouring agent and confirms that JECFA evaluated paprika extract for use as a colour. EX-1034, 1, 6.

158. Accordingly, Watanabe discloses *the active ingredient includes one or more constituent components, at least one of which is among one or more principle molecular types from which at least one of a desirable food, flavor, fragrance, medicament, and pigment is obtained*. EX-1006, [0001], [0006], [0053], [0055]–[0056].

[10c] a weight percentage of at least one of the one or more principle molecular types in the active ingredient does not vary by more than about 5% during aging of the dried powder during any period of elevated temperature of about 95°F up to about 1000 hours.

159. Watanabe-JECFA References render obvious *a weight percentage of at least one of the one or more principle molecular types (e.g., capsanthin) in the active ingredient (e.g., paprika oil) does not vary by more than about 5% during aging of the dried powder (e.g., 2.5% variation — 97.5% retention) during any period of elevated temperature of about 95°F up to about 1000 hours (e.g., 672 hours at 122°F (50°C), an elevated temperature in excess of about 95°F).*

160. As explained above for [10b], capsanthin is a *principle molecular type* of paprika oil (the *active ingredient* of Example 5’s spray-dried powder) and the molecule from which the powder’s desirable red pigment is obtained. [10b]; EX-1006, [0053]. Watanabe’s Reference Example 3 measured that powder’s stability: Watanabe stored the Example 5 powder in a low-density polyethylene bag, in the dark, at 122°F (50°C) for four weeks (672 hours), and measured its residual “paprika pigment” by spectrophotometry against the powder’s own pigment content measured immediately after preparation, which Watanabe sets at 100%. EX-1006, [0055]–[0058], Table 3. On that basis, Table 3 reports 97.5% retention—a 2.5% variation in paprika pigment over 672 hours at 122°F (50°C). EX-1006, Table 3.

161. As explained below, a POSITA would have understood that the weight percentage of capsanthin—one of *the principle molecular types in the active ingredient—does not vary by more than about 5% during aging of the dried powder*. For context, paprika pigment is a mixture of several carotenoid constituent components, which fall into two color groups: a red group (chiefly capsanthin, together with capsorubin, the *Capsicum*-specific carotenoids that give paprika its characteristic red color); and a yellow group (such as β -carotene and zeaxanthin). EX-1033, 51, 56; EX-1034, 3–4. *See, e.g.*, EX-1021; EX-1018; EX-1019. Capsanthin is the single most abundant carotenoid and the largest contributor to paprika oil’s red color. EX-1033, 51–52; EX-1034, 3–4.

162. With this context, Watanabe's spectrophotometric assay does not measure any one of these carotenoids separately; it measures the light absorbed by all of them together and reports that combined signal as a single paprika-pigment number. EX-1006, [0055]-[0056]. Such a measurement is conventionally expressed in capsanthin equivalents. EX-1033, 51-52, 54-56. In other words, the total color is stated as though it all came from capsanthin, the largest contributor and the standard reference point for reporting total paprika color.

163. Because the reported figure is a combined signal, the measured 97.5% retention is a weighted average of how well the individual carotenoids were retained—i.e., each carotenoid counts toward the 97.5% in proportion to its share of the original color. Two consequences follow from this. First, if the weighted average is 97.5%, at least one carotenoid would be retained at 97.5% or more, because an average cannot be 97.5% if every contributor to the average falls below 97.5%. Second, because the red group (including capsanthin) makes up roughly half of the total color signal (*see* EX-1022; EX-1018), that group must have been retained at approximately 95% or more (since the whole sample lost only 2.5%, even assigning that entire loss to the red group alone amounts to just a 5% loss within a group that is half the signal).

164. Capsanthin's own variation, in turn, would not have exceeded the measured 2.5% loss. The red carotenoids, including capsanthin, are recognized to

degrade more slowly than the yellow carotenoids under these dry, dark storage conditions at temperatures below 60°C; the faster-degrading yellow carotenoids therefore would account for more than their proportional share of the 2.5% loss, leaving capsanthin's own loss at or below 2.5%. *See, e.g.*, EX-1023; EX-1024; EX-1025. Nevertheless, even setting aside the relative stability of the red and yellow carotenoids, the arithmetic alone establishes that the red group—of which capsanthin is the dominant member—was retained at approximately 95% or more, because assigning the entire 2.5% total loss to a red group comprising roughly half the signal yields only about a 5% loss within that group. Capsanthin's variation thus falls within the *about 5%* ceiling of [10c] under either analysis: at or below about 2.5% accounting for the slower degradation of the red carotenoids, and no more than about 5% on the arithmetic alone.

165. The carotenoid makeup of paprika pigment, and the way Watanabe's spectrophotometric assay reflects it, can be stated more specifically. As of the priority date (September 2010) it was well understood that ripe red paprika contains dozens of carotenoids, of which capsanthin is the single most abundant—typically about 30% to 60% of the total carotenoids, and exceeding 50% in some cultivars. EX-1018 (Deli); EX-1019 (Topuz & Ozdemir); EX-1034 (JECFA CTA). A representative composition, expressed as a share of total carotenoids, is shown below:

Carotenoid	% of total	Isochromic fraction
Capsanthin	37%	Red (Capsicum-specific); largest single constituent
β -Carotene	9%	Yellow
Zeaxanthin	8%	Yellow
Cucurbitaxanthin A	7%	Yellow
Capsorubin	3.2%	Red (Capsicum-specific)
Remainder (capsanthin epoxides, violaxanthin, antheraxanthin, β -cryptoxanthin, cis-isomers)	~35.8%	Mixed (includes red Capsicum-specific epoxides)

Representative values (Deli et al. (2001), EX-1018; reproduced in the JECFA CTA evaluation, EX-1034). Exact percentages vary with cultivar, ripeness, and whether the material is fresh fruit, dried paprika, or an oleoresin.

166. These pigments divide into two color-based (isochromic) groups: a red, Capsicum-specific fraction (capsanthin, capsorubin, and the capsanthin epoxides that make up part of the compositional remainder) and a yellow fraction (β -carotene, zeaxanthin, violaxanthin, antheraxanthin, β -cryptoxanthin, and cucurbitaxanthin A). EX-1021 (Hornero-Méndez & Mínguez-Mosquera). Because part of the remainder consists of capsanthin epoxides—themselves red, Capsicum-specific pigments—the red ketocarotenoid fraction is larger than capsanthin’s share alone would indicate.

167. Each carotenoid contributes to the measured signal according to both its concentration and how strongly it absorbs at the roughly 460 nm analysis wavelength. The major paprika carotenoids have similar absorptivities— $A(1\%, 1\text{ cm}) \approx 2,000\text{--}2,600$ at their absorption maxima, which fall within a narrow 450–485 nm range in acetone—so each contributes to the 460 nm signal roughly in proportion to its concentration, to within about $\pm 10\text{--}15\%$. EX-1022 (Britton); EX-1033 (JECFA Monograph). On that basis, the estimated share of the 460 nm absorbance signal is:

Carotenoid or grouping	Est. share of ~460 nm absorbance
Capsanthin (including capsanthin epoxides)	~40–55%
Capsorubin	~3–5%
β -Carotene	~9–11%
Zeaxanthin	~8–10%
Cucurbitaxanthin A	~6–7%
Violaxanthin, antheraxanthin, β -cryptoxanthin, minor	balance

Estimated from the composition above and reported carotenoid absorptivities (Britton, EX-1022). The red ketocarotenoids together account for roughly half of the total absorbance, with capsanthin by far the largest individual contributor.

168. These shares make the retention arithmetic clearer. Letting w_i be each carotenoid's initial share of the total 460 nm signal ($\sum w_i = 1$) and r_i its fractional retention after storage, Watanabe's retained pigment signal is the absorbance-weighted average of the individual retentions: $\sum (w_i \cdot r_i) = 0.975$. This treats the measured pigment value as reflecting genuine carotenoid retention—an assumption supported by the direction of carotenoid degradation chemistry, which shortens or disrupts the conjugated polyene chromophore and thereby shifts absorption toward shorter wavelengths and reduces, rather than adds to, absorbance near 460 nm. EX-1022 (Britton); EX-1029 (Mínguez-Mosquera & Jarén-Galán).

169. Two consequences follow. First, as a matter of arithmetic, at least one carotenoid must have retained 97.5% or more of its initial contribution, because a weighted average cannot equal 0.975 if every value averaged is below 0.975. Second, the larger a component's or group's initial share w of the signal, the higher the floor on its retention: a component or group initially contributing a fraction w of the signal must have retained at least $r \geq 1 - 0.025/w$. For a group that is half the

signal ($w = 0.5$), that floor is $1 - 0.025/0.5 = 0.95$ (95.0%); for one that is 70% of the signal, it is about 96.4%.

170. Applying that floor to the red ketocarotenoid fraction—which, as shown above, is roughly half of the signal—that fraction must have been retained at approximately 95% or more, and therefore at least one of its principal members (capsanthin or capsorubin) must likewise have been retained at approximately 95% or more. The floor is higher still for capsanthin once its recognized slower degradation relative to the yellow carotenoids is credited. Treating the small set of clearly more stable components (of combined signal share w_M) as retained at least as well as capsanthin, capsanthin's minimum retention is $r(\text{capsanthin}) \geq (0.975 - w_M) / (1 - w_M)$. Taking capsorubin as the only clearly more stable significant component ($w_M \approx 0.03\text{--}0.05$) gives a capsanthin floor of about 97.4%; including zeaxanthin and violaxanthin as well ($w_M \approx 0.12$) still gives about 97.2%—in each case essentially the overall 97.5% retention. EX-1023 (Jarén-Galán & Mínguez-Mosquera); EX-1024, EX-1025 (Pérez-Gálvez); EX-1026 (Topuz & Ozdemir). This quantitatively confirms the conclusion stated above: capsanthin's own variation over Watanabe's 672-hour test at 122°F (50°C) is about 2.5% or less, well within [10c]'s about 5% ceiling.

171. Watanabe further discloses or at least renders obvious that this stability occurred *during aging of the dried powder during an elevated temperature of about*

95°F. Watanabe aged the dried Example 5 powder at 122°F (50°C)—an elevated temperature that meets and substantially exceeds the ***about 95°F*** recited in the claim. EX-1006, [0055]–[0058], Table 3. Although that temperature is hotter than the “about 95°F” recited in [10c], it would have been obvious to a POSITA that a powder exhibiting only about 2.5% capsanthin variation at the harsher 122°F would exhibit no greater variation at the milder claimed 95°F. That is because the rate of carotenoid degradation increases with temperature and falls as temperature falls. EX-1007 (Singh) at 14–15, 19, Fig. 1.9; EX-1012 (Bechoff), at 354. Thus, a powder losing no more than about 2.5% of its capsanthin over 672 hours at 122°F cannot lose more than that amount over the same period at the cooler claimed 95°F; the lower temperature can only slow the degradation—not accelerate it. A POSITA would thus recognize that the claimed condition is gentler than the condition Watanabe actually tested. And because the Example 5 powder a POSITA would assess at 95°F is the identical powder Watanabe tested at 122°F, no modification of the powder is required—only the storage temperature differs.

172. Indeed, elevated-temperature stability testing of the kind Watanabe performed is the established, routine technique formulation scientists used as of the priority date (September 2010) to bound an ingredient’s stability at the lower temperatures of ordinary storage. EX-1007 at 14-19; EX-1013 (Labuza) at Ch. 16. Thus, a stability test executed at a much higher temperature of 50°C would

conservatively bound the loss the same powder will experience at lower temperatures. *Id.* Thus, in view of Watanabe, a POSITA would have been motivated by the recognized purpose of accelerated testing, to recognize that result as establishing the powder's stability at the gentler about 95°F condition. Moreover, because degradation rate decreases as temperature decreases for the same tested powder, a POSITA would have had a reasonable expectation of success that capsanthin's variation at about 95°F would be no greater than the about 2.5% Watanabe measured at 122°F. This would have amounted to applying a known technique (accelerated stability testing) to a known powder (Example 5) to obtain the expected outcome (at least as much retention at the lower temperature). This assessment is confirmed by the three analyses presented below, each of which independently projects capsanthin's variation at 95°F well within the about 5% ceiling recited in the claim. Accordingly, Watanabe discloses or at least renders obvious that the stability occurs or would have occurred *during aging of the dried powder during an elevated temperature of about 95°F.*

173. Finally, Watanabe renders obvious that the weight percentage of capsanthin would not vary by more than about 5% *during any period* of elevated temperature of about 95°F *up to about 1000 hours.* Watanabe measured capsanthin retention over 672 hours at 122°F (50°C), finding variation of no more than about 2.5%. EX-1006, [0055]–[0058], Table 3. While Watanabe did not test for the about

1,000 hours that [10c] recites, it would have been obvious to a POSITA, applying the routine predictive tools of the formulation art to Watanabe's data, that the same powder's capsanthin variation remains within about 5% out to about 1,000 hours.

174. A POSITA developing or evaluating a spray-dried flavor or pigment powder would have been motivated to confirm that the encapsulated active remains stable across a commercially meaningful warm-storage shelf life on the order of about 1,000 hours (roughly six weeks). EX-1006, [0011]; EX-1013 (Labuza), Ch. 3. Projecting longer-term storage stability from a shorter elevated-temperature test is the recognized purpose of accelerated stability testing—the standard method a formulator uses to predict shelf life. EX-1007 at 14-19; EX-1013, Ch. 3. A POSITA presented with Watanabe's 672-hour, 50°C result would thus, in the ordinary course, have been motivated to project it to the storage durations of practical interest, including about 1,000 hours.

175. A POSITA would also have had a reasonable expectation in that projection and expected that the result of that projection would fall within the claimed about 5% ceiling. Capsanthin degrades in spray-dried, dark-stored matrices by first-order kinetics, losing a roughly constant fraction of whatever remains per unit time. EX-1027 (Topuz 2008), at 1672, 1674; EX-1012 (Bechoff), at 354; EX-1014 (Palma). Because the loss rate does not accelerate over the relevant window, extending Watanabe's measured 672-hour loss to 1,000 hours conservatively bounds

the variation a POSITA would expect, rather than understating it. Extending a known first-order rate from 672 to 1,000 hours is the predictable application of a known kinetic model to known data: the claimed ~1,000-hour durability is what a POSITA would have predicted for this powder using ordinary tools.

176. A POSITA would have confirmed that expectation quantitatively, and three independent analyses (increasingly favorable to Petitioner) each place capsanthin's variation over 1,000 hours at 95°F well within the about 5% ceiling.

177. First, the simplest of the three analyses takes the loss rate Watanabe actually measured and projects it forward to the full 1,000-hour period, while giving no credit for the fact that the claim's 95°F condition is cooler (and therefore a gentler test) than Watanabe's 122°F (50°C) test temperature. Even so, the projected variation is only about 3.7%, within the **about 5%** requirement recited in [10c]. This analysis is based on first-order kinetics, the established way carotenoids such as capsanthin degrade in spray-dried matrices: the ingredient loses a roughly constant fraction of whatever remains over time. EX-1027 (Topuz 2008), at 1672, 1674; EX-1012 (Bechoff), at 354. If a first-order ingredient loses a constant fraction of what remains over time, the total loss grows in step with the length of the aging period. This then conservatively extends Watanabe's measured loss from its 672-hour test to the longer 1,000-hour period, yielding a modestly larger loss of about 3.7%. This is the most conservative reading of the data because it holds Watanabe's harsher

122°F (50°C) condition fixed. A POSITA would appreciate that accounting for the cooler 95°F claim temperature would only reduce the projected loss further.

178. Second, applying the standard Arrhenius temperature correction—the accepted method for translating a degradation rate measured at one temperature to the expected rate at another—and accounting for the cooler 95°F claim condition, the projected variation is only about 1.1%. The Arrhenius framework is based on the principle that degradation reactions slow as temperature falls and an ingredient’s “activation energy” measures how steeply they slow (e.g., the higher the activation energy, the greater the slowdown at the lower temperature). Singh (EX-1007), at 14-19. A POSITA would have understood or found obvious to apply the Arrhenius correction here to quantify the degradation of Watanabe’s test, which ran at the hotter 122°F (50°C), to the milder 95°F temperature recited in the claim.

179. For purposes of running the Arrhenius evaluation, a POSITA would have sought the activation energy of the principle molecular type (capsanthin), which was reported in Palma—a study of the same molecule in spray-dried, dark-stored, microencapsulated paprika oleoresin, tested across 104–158°F (40–70°C, bracketing Watanabe’s 122°F) under confirmed first-order kinetics. EX-1014 (Palma). Applying that value, the cooler 95°F claim temperature slows capsanthin’s degradation enough that its projected variation over the full 1,000-hour period is only about 1.1%, comfortably within the ***about 5%*** claimed loss threshold.

180. Although Palma postdates the assumed September 2010 priority date, the activation energy it reports is a fixed physicochemical property (activation energy) of the capsanthin molecule that was necessarily present in Example 5 powder when it was made; Palma is therefore evidence of an inherent property of that powder. Nevertheless, this Arrhenius result is independently corroborated by pre-priority-date literature, including Bechoff. Bechoff reports an activation energy for β -carotene—a structurally related carotenoid—degrading by first-order kinetics in a dried food matrix under conditions similar to Watanabe’s spray-dried, dark-stored system. EX-1012 (Bechoff), at 354. Applying Bechoff’s activation energy to capsanthin by structural analogy yields essentially the same projected variation—about 1.1%—confirming that the conclusion holds even applying Bechoff’s pre-priority date activation energy.

181. Third, even using the lowest temperature dependence in the food-stability literature, capsanthin’s projected variation stays within the ceiling. Q_{10} — the factor by which a degradation rate changes per 18°F (10°C) of temperature— provides a simplified temperature correction; a larger Q_{10} gives more credit for the lower claim temperature. Applying a conservative Q_{10} of about 1.5—below the values implied by Palma and Bechoff (≈ 2.2 – 2.3) and at the low end of the published range for slowly degrading foods (Labuza reports 1.39–1.63 for instant coffee)— capsanthin’s projected variation at 95°F over 1,000 hours is no more than about

2.0%. EX-1013 (Labuza), Ch. 16 & Tbl. 16.1.

182. The arithmetic underlying these three analyses is straightforward and rests on Watanabe's own measured data. For first-order degradation, the retained fraction after time t is $C(t)/C_0 = \exp(-k \cdot t)$. Watanabe's 97.5% retention (0.975) after 672 hours at 122°F (50°C) fixes the degradation rate constant at that temperature: $k_{50} = -\ln(0.975)/672 = 3.77 \times 10^{-5} \text{ h}^{-1}$. EX-1006, Table 3; EX-1027 (Topuz 2008); EX-1012 (Bechoff).

183. *First (no temperature credit)*. Holding that 122°F (50°C) rate fixed and projecting to 1,000 hours—giving no credit for the cooler claimed 95°F condition—the retained fraction is $C_{1000}/C_0 = \exp[-(3.77 \times 10^{-5})(1,000)] = 0.9630$, a projected loss of about 3.70%. A simple linear extrapolation of the measured loss gives essentially the same result, $2.5\% \times (1,000/672) \approx 3.72\%$. Either way the projected 1,000-hour loss is within [10c]'s about 5% ceiling, and it holds even for an apparent activation energy of zero ($Q_{10} = 1.0$).

184. *Second (Arrhenius, crediting the cooler claim temperature)*. The Arrhenius relationship translates a rate measured at one temperature to another: $k_{50}/k_{35} = \exp[(E_a/R)(1/T_{35} - 1/T_{50})]$, with $T_{35} = 308.15 \text{ K}$, $T_{50} = 323.15 \text{ K}$, and $R = 8.314 \text{ J} \cdot \text{mol}^{-1} \cdot \text{K}^{-1}$. Palma reports capsanthin's activation energy in the closest-matching system (unsaponified, spray-dried, dark-stored paprika oleoresin, tested across 40–70°C under confirmed first-order kinetics) as 15.9 kcal/mol, or about 66.5

kJ/mol. EX-1014 (Palma). That value gives $k_{50}/k_{35} = \exp[(66,526/8.314)(1/308.15 - 1/323.15)] = 3.34$, so Watanabe's 672-hour exposure at 122°F (50°C) corresponds to about 2,243 hours at the claimed 95°F (35°C). The 95°F rate is then $k_{35} = k_{50}/3.34 = 1.13 \times 10^{-5} \text{ h}^{-1}$, and the retained fraction over 1,000 hours is $\exp[-(1.13 \times 10^{-5})(1,000)] = 0.9888$ —a projected loss of about 1.12% (about 1.11% by the small-loss approximation $2.5\% \times (1,000/2,243)$). This is the about 1.1% figure, comfortably within the about 5% ceiling and also below the about 2% ceiling of claim 17.

185. *Third (conservative Q_{10} floor).* Q_{10} —the factor by which the rate changes per 18°F (10°C)—provides a simplified correction; capsanthin's measured activation energy corresponds to $Q_{10} = \exp[(E_a/R)(1/308.15 - 1/318.15)] \approx 2.26$, consistent with the ≈ 2.2 – 2.3 range implied by the paprika-specific literature. EX-1014 (Palma); EX-1012 (Bechoff). Using instead a deliberately conservative Q_{10} of about 1.5—at the low end of the published range for slowly degrading foods (EX-1013 (Labuza), Ch. 16 & Tbl. 16.1) and well below the paprika-specific values—the rate ratio is $k_{50}/k_{35} = 1.5^{1.5} \approx 1.84$, so 672 hours at 122°F (50°C) corresponds to about 1,235 hours at 95°F, and the projected 1,000-hour loss is $2.5\% \times (1,000/1,235) \approx 2.0\%$.

Temperature-dependence assumption	Basis	Projected loss at ~1,000 h
No temperature credit ($Q_{10} = 1.0$, $E_a = 0$)	Watanabe rate held fixed	~3.7%
Conservative Q_{10} floor (≈ 1.5)	Labuza (EX-1013)	~2.0%

Temperature-dependence assumption	Basis	Projected loss at ~1,000 h
Capsanthin Arrhenius ($E_a \approx 66.5$ kJ/mol; $Q_{10} \approx 2.26$)	Palma (EX-1014)	~1.1%

186. In summary, all three analyses are within the claimed 5% range —about 3.7% on the most conservative assumptions, about 2.0% at a conservative Q_{10} floor, and about 1.1% at capsanthin’s measured activation energy. And, all three analyses leverage well known and conventional techniques (e.g., first-order kinetics, the Arrhenius relationship, and Q_{10} scaling) applied to Watanabe’s own measured data together with parameters drawn from the literature. EX-1007 (Singh); EX-1027 (Topuz 2008); EX-1012 (Bechoff); EX-1013 (Labuza).

187. Alternatively, if “during any period ... up to about 1000 hours” sets the *maximum* length of the aging period rather than a minimum, Watanabe discloses the limitation. Reference Example 3 aged the Example 5 powder for 672 hours—a period “up to about 1000 hours” (i.e., about 1,000 hours or shorter)—with capsanthin varying by no more than about 2.5% across that entire period. That is well within the claimed ***about 5%*** ceiling. EX-1006, [0055]–[0058], Table 3. Watanabe thus discloses a ***principle molecular type*** whose weight percentage stays within about 5% of its starting value across an aging period of about 1,000 hours or less at the requisite elevated temperature.

188. For at least the above reasons, Watanabe discloses or renders obvious a ***weight percentage of at least one of the one or more principle molecular types***

(capsanthin) *in the active ingredient* (paprika oil) *does not vary by more than about 5% during aging of the dried powder during any period of elevated temperature of about 95°F up to about 1000 hours*. EX-1006, [0053], [0055]–[0058], Table 3.

Dependent Claim 11

[11] The spray dried powder of claim 10, wherein the one or more principle molecular types are molecular types of a food composition.

189. Watanabe-JECFA References render obvious that *the one or more principle molecular types are molecular types of a food composition* (e.g., capsaanthin, the principle molecular type identified above with respect to [10b] from which the paprika red color is obtained).

190. Watanabe teaches that its powder compositions—including the Example 5 paprika-containing powder—are designed for incorporation into “various drinks, foods, cosmetics and the like.” EX-1006, [0001], [0006], [0053]. Capsanthin, the principle molecular type identified at [10b], is so incorporated into food and is itself a permitted food colorant in commercial paprika oleoresin used as a food coloring. Capsanthin is therefore a molecular type of *a food composition*. Watanabe accordingly discloses the limitation of claim 11. [10b]; EX-1006, [0001], [0006], [0053].

Dependent Claim 15

[15] The spray dried powder of claim 10, wherein the one or more principle molecular types are molecular types of a pigment composition.

191. Watanabe-JECFA References render obvious that *the one or more principle molecular types are molecular types of a pigment composition* (e.g., capsanthin, the principle molecular type identified above with respect to [10b]).

192. Watanabe expressly identifies “*coloring agents*” as one of the categories of active component its powder compositions are designed to carry. EX-1006, [0001], [0006], [0008]–[0009]. Capsanthin is itself the principal red pigment of paprika oil — the molecule from which paprika’s characteristic red color is obtained — and is the principal constituent measured by Watanabe’s spectrophotometric “*paprika pigment*” assay in Reference Example 3, used by Watanabe as the indicator of the powder’s coloring performance. EX-1006, [0055]–[0056], Table 3. Capsanthin is therefore a molecular type of *a pigment composition* within the meaning of claim 15.

Dependent Claim 16

[16] The spray dried powder of claim 10, wherein the weight percentage of at least one of the one or more principle molecular types in the active ingredient does not vary by more than about 3% during aging of the dried [powder]

during any period of elevated temperature of about 95°F up to about 1000 hours.

193. Watanabe-JECFA References render obvious claim 16 for the reasons in [10c]. As explained above in [10c], during aging of the dried powder at an elevated temperature in excess of about 95°F for a period up to about 1000 hours (e.g., 672 hours at 122°F (50°C)), capsanthin—a principle molecular type of the paprika oil active ingredient—exhibits about 97.5% retention, i.e., a variation of about 2.5%. Thus, as explained in [10c], a POSITA would have found obvious that the weight percentage of capsanthin (i.e., *the at least one of the one or more principle molecular types in the active ingredient*) varies by about 2.5% during such aging—and thereby *does not vary by more than about 3% during aging of the dried powder during any period of elevated temperature of about 95°F up to about 1000 hours.*

Dependent Claim 17

[17] The spray dried powder of claim 10, wherein the weight percentage of at least one of the one or more principle molecular types in the active ingredient does not vary by more than about 2% during aging of the dried [powder] during any period of elevated temperature of about 95°F up to about 1000 hours.

194. Watanabe-JECFA References render obvious claim 17 for the reasons

in [10c]. As explained above in [10c], during aging of the dried powder at an elevated temperature in excess of about 95°F for a period up to about 1000 hours (e.g., 672 hours at 122°F (50°C)), capsanthin—a principle molecular type of the paprika oil active ingredient—exhibits about 97.5% retention, i.e., a variation of about 2.5%.

195. Thus, as explained in [10c], a POSITA would have found obvious that the weight percentage of capsanthin (i.e., *the at least one of the one or more principle molecular types in the active ingredient*) varies by about 2.5% at the harsher 122°F (50°C) condition that Watanabe actually tested. As explained in [10c], projecting that measured loss to the milder claimed condition (about 95°F over about 1,000 hours) using capsanthin's activation energy under the Arrhenius framework yields a projected variation of only about 1.1%. That projected variation is comfortably below the about 2% ceiling of claim 17, such that capsanthin *does not vary by more than about 2% during aging of the dried powder during any period of elevated temperature of about 95°F up to about 1000 hours*.

Dependent Claim 19

[19] The spray dried powder of claim 10, wherein the carrier comprises starch.

196. Watanabe-JECFA References render obvious that *the carrier comprises starch* (e.g., the trehalose/water-soluble hemicellulose carrier of Watanabe's powder composition may further contain starch, starch syrup, and starch

hydrolyzates and starch derivatives such as dextrin, as taught at EX-1006, [0018]).

197. As shown above with respect to [10a], the *carrier* of Watanabe's spray-dried powder is the carbohydrate matrix that surrounds the paprika oil active ingredient. [10a]; EX-1006, [0008]–[0009], [0044], [0053]. Watanabe expressly teaches that the carrier composition “may further contain sugars such as sucrose, lactose, glucose, starch syrup and reduced starch syrup; sugar alcohols; various starch hydrolyzates and starch derivatives (e.g., dextrin); starch; gelatin; natural gums such as gum arabic; and the like.” EX-1006, [0018]. Watanabe further teaches that “[t]he contents of these additives may be suitably chosen according to the properties desired for the powder composition.” EX-1006, [0018]. Watanabe's disclosed carrier compositions accordingly encompass embodiments in which the carrier comprises starch alongside the trehalose and water-soluble hemicellulose.

C. Ground 3: Subramaniam Renders Obvious Claims 1-5, 7-14, and 16-19

Independent Claim 1

[1pre] A spray dried powder, comprising:

198. If the preamble is limiting, Subramaniam discloses *a spray-dried powder*.

199. Subramaniam's stated invention is “a composition in the form of a spray-dried powder, comprising one or more active ingredients dispersed in a carrier.” EX-1004, [0020]; *see also id.*, [0014].

200. The invention is “described in a more detailed manner” in various examples. EX-1004, [0048]. Example 5 of Subramaniam discloses a spray-dried powder “prepared” using a method “described in Example 1.” EX-1004, [0060]. The Example 1 method first prepares a wet batch by “hydrating agar agar in water . . . and subsequently mixing it with the rest of the ingredients” and homogenizing the batch. EX-1004, [0050]. This batch is then “dried with a Leafflash apparatus characterized by the respective inlet/outlet temperatures of 180/80°” to obtain a spray-dried powder. EX-1004, [0051], [0060]-[0061].

201. Accordingly, Subramaniam discloses *a spray-dried powder*. EX-1004, [0001], [0004]-[0005], [0014], [0016], [0020], [0048], [0050]-[0051], [0060]-[0061].

[1a] a plurality of dried particles, which individually contain an amount of final active ingredient encapsulated within a carrier resulting from drying a slurry containing an initial active ingredient, a liquid solvent and the carrier, wherein:

202. Subramaniam discloses *a plurality of dried particles* (e.g., Example 5’s spray-dried particulates) *which individually contain an amount of final active ingredient* (e.g., an amount of fragrance recovered from Example 5’s spray-dried powder) *encapsulated within a carrier* (e.g., maltodextrin/sucrose/agar agar carrier) *resulting from drying a slurry* (e.g., drying of Example 5’s aqueous emulsion)

containing an initial active ingredient (e.g., fragrance as loaded into the aqueous emulsion), *a liquid solvent* (e.g., water) *and the carrier* (e.g., maltodextrin, sucrose and agar agar carrier materials dispersed in the aqueous emulsion).

203. Subramaniam's stated invention is "a composition in the form of a spray-dried powder, comprising one or more active ingredients dispersed in a carrier, wherein said carrier comprises at least one wall-forming carbohydrate material and from 1 to 30% of agar agar, relative to the dried weight of the composition." EX-1004, [0020]. Subramaniam further teaches that, "[i]n spray-dried powders, an active ingredient such as a flavor or a fragrance, usually hydrophobic, is entrapped as liquid droplets in a solidified matrix of a dehydrated carrier, generally consisting of carbohydrates, such as starches, hydrolyzed starches (maltodextrin), chemically modified starches, emulsifying polymers (gum arabic) and in certain instances monomers and dimers of simple aldohexoses, or any combination thereof." EX-1004, [0005].

204. The invention's composition is initially prepared as a *slurry*—specifically, an aqueous emulsion. EX-1004, [0030]. The composition "is initially in the form of an aqueous emulsion" and "contains, before being spray-dried, from 50 to 90% of water, preferably from 60 to 85% by weight of water, relative to the total weight of the emulsion." EX-1004, [0030]. Water is the *liquid solvent*. EX-1004, [0030], [0050].

205. Example 5's aqueous emulsion is prepared from a composition consisting of 29.70% maltodextrin 18DE, 29.70% sucrose, 10.00% agar agar, 0.60% lecithin, and 30.00% fragrance (origin: Firmenich SA, Geneva, Switzerland) by dry weight, homogenized in water to a solid content of 33.98%. EX-1004, [0060]-[0061]. The fragrance loaded into that aqueous emulsion is the *initial active ingredient*. EX-1004, [0060]. The carrier materials (maltodextrin 18DE, sucrose, and agar agar) are dispersed in the aqueous emulsion as required by [1a]. EX-1004, [0050], [0060]. The Example 5 powder, which is prepared according to the Example 1 method, is emulsified by “hydrating agar agar in water (approximately 10% solids level) and subsequently mixing it with the rest of the ingredients” in a stainless kettle with pneumatic agitation, maintaining the batch temperature at 65-70°C, and homogenizing at 7000 kPa. EX-1004, [0050]; [0060].

206. The aqueous emulsion is then spray dried using a Leafflash apparatus operating at 180°C inlet and 80°C outlet temperatures. EX-1004, [0051]; [0060]. The drying step produces dried particles in which an amount of the active ingredient is encapsulated within the carrier. EX-1004, [0005], [0053], [0060]. Microscopy of the resulting particulates confirms that the active ingredient is encapsulated within the carrier on a particle-by-particle basis. EX-1004, [0053].

207. The below table shows the formulation of Example 5's pre-spray-dried composition (“% dry” column) and when made into a slurry (“Grams” column,

which adds water). EX-1004, [0059]-[0060]. In particular, the table lists relative dry weight and weight in grams of the active ingredient (fragrance) and of the carrier, which includes wall-forming carbohydrate materials (maltodextrin, sucrose) and agar agar. EX-1004, [0020], [0060]-[0061].

Subramaniam (EX-1004), Example 5 (annotated)		
Ingredients	Grams	% dry
Maltodextrin 18DE	2079	29.70
Sucrose	2079	29.70
Agar agar	700	10.00
Fragrance ¹⁾	2100	30.00
Lecithin	42	0.60
Water	13600	
Total		100.00
1) origin : Firmenich SA, Geneva, Switzerland		
= carrier (maltodextrin, sucrose, agar agar) = active ingredient (fragrance)		

208. Accordingly, Subramaniam discloses *a plurality of dried particles, which individually contain an amount of final active ingredient encapsulated within a carrier resulting from drying a slurry containing an initial active ingredient, a liquid solvent and the carrier*. EX-1004, [0005], [0015]-[0016], [0020], [0030], [0050]-[0053], [0060]-[0061].

[1b] the initial active ingredient includes one or more constituent components, at least one of which is among one or more principle molecular types from

which at least one of a desirable food, flavor, fragrance, medicament, and pigment is obtained;

209. Subramaniam discloses or renders obvious that *the initial active ingredient* (e.g., Example 5's fragrance as loaded into the aqueous emulsion) *includes one or more constituent components* (e.g., the fragrance's constituent perfuming ingredients), *at least one of which is among one or more principle molecular types* (e.g., one or more principal, character-imparting constituent of the fragrance) *from which at least one of a desirable fragrance is obtained* (e.g., Example 5's fragrance).

210. Example 5's *initial active ingredient* is the "fragrance" as loaded into the aqueous emulsion. EX-1004, [0059]-[0060].

Subramaniam (EX-1004), Example 5 (annotated)		
Ingredients	Grams	% dry
Maltodextrin 18DE	2079	29.70
Sucrose	2079	29.70
Agar agar	700	10.00
Fragrance ¹⁾	2100	30.00
Lecithin	42	0.60
Water	13600	
Total		100.00
1) origin : Firmenich SA, Geneva, Switzerland		
= carrier (maltodextrin, sucrose, agar agar) = active ingredient (fragrance)		

211. Example 5's fragrance (initial active ingredient) *includes one or more constituent components*. A POSITA would have understood that a commercial "fragrance" of the type used in Example 5 is a multi-component mixture of perfuming ingredients (e.g., aroma chemicals, essential oils, and aromatic isolates) formulated together to produce a characteristic odor profile. Each such perfuming ingredient is a constituent component of the fragrance.

212. That understanding is consistent with and corroborated by Subramaniam's Example 7, showing that a "perfume composition" has multiple perfuming ingredients (there, five—benzyl acetate, phenylethyl acetate, cyclamen aldehyde, Lilial®, and hexyl salicylate), EX-1004, [0065], n.1. Subramaniam also refers to such perfuming ingredients as active-ingredient constituents quantified in its retention analyses. EX-1004, [0067] (describing GC-MS analysis "to determine the residual quantity of the various perfuming ingredients"); EX-1004, [0068] (referring to "the highest proportion of perfuming ingredients which have not been decomposed"); EX-1004, Table 1 (titled "Percentage of perfume ingredients recovered"). This understanding is consistent with the '776 patent, which discloses that "[t]he active ingredient may be any desirable single constituent component or a combination of constituent components," "desirable" meaning at least one of said components provide the desired "flavor, fragrance," etc. EX-1001, 6:10–15. For example, the '776 patent identifies D-limonene as a "particular constituent

component” of orange oil. EX-1001, 12:18–21, Fig. 11; *see also id.* 12:9–34 (Fig. 11 accelerated-aging discussion).

213. *At least one of the constituent components* of Example 5’s initial active ingredient (the fragrance) *is among one or more principle molecular types from which the desirable fragrance is obtained*. Essentially, at least one of the constituent components of Example 5’s initial active ingredient (the fragrance) is a primary or major fragrance-imparting/-contributing constituent. While Subramaniam does not expressly list each constituent component of Example 5’s active ingredient (fragrance from “Firmenich SA”), a POSITA would have understood or found obvious that the fragrance includes *one or more constituent components* from which the desired fragrance (i.e., scent) is obtained. For example, Subramaniam confirms that the fragrance, i.e., its active ingredient, “may include volatile perfuming or flavoring ingredients, as well as other kinds of ingredients such as pharmaceutical actives.” EX-1004, [0015]. Subramaniam further discloses that “the active ingredient” of its “spray-dried composition” is “preferably ... [a] fragrance ingredient or composition” (EX-1004, [0031]), which includes a “variety” of “fragrance materials,” both natural and synthetic origin, that may be “single compounds and mixtures” and that are “well known” in the art for “imparting an odor and/or a flavor or taste to a consumer product traditionally perfumed or flavored” or for “modifying the odor and/or taste.” EX-1004, [0032].

214. Consistent with this, Subramaniam directs a person of ordinary skill to Fenaroli's Handbook of Flavor Ingredients as a source of "specific examples of such components." EX-1004, [0032]; EX-1036, 99. I have reviewed that reference. Fenaroli's catalogs, in individual monographs, the discrete flavor and aroma compounds used to impart or modify flavor and odor, giving for each its chemical identity, structure, physical properties, and regulatory status. For example, Fenaroli's monograph for citral (3,7-dimethyl-2,6-octadienal; $C_{10}H_{16}O$) identifies a single, well-characterized molecular compound—a lemon-note aldehyde used in flavor and fragrance compositions—listed as FDA GRAS, FEMA No. 2303. EX-1036, 99. In my opinion, a POSITA consulting this reference as of the priority date would have understood that the "volatile or labile components in liquid form, preferably hydrophobic" that Subramaniam encapsulates are discrete, individually identifiable molecular compounds—for example, citral, ethyl butyrate, isoamyl acetate, and myrcene—each a single molecular type from which a characteristic flavor or fragrance is obtained. EX-1004, [0032]; EX-1036, 99. This confirms that the active ingredient of Subramaniam's spray-dried composition comprises one or more principle molecular types, as [1b] requires.

215. While Subramaniam does not name the individual constituents of the Example 5 Firmenich fragrance, [1b] does not require such specific identification; it requires only that the active ingredient include at least one constituent that is a

principle molecular type—a principal, character-imparting constituent from which the desired fragrance is obtained (explained above). A POSITA would have understood that a commercial fragrance of the type used in Example 5 contains at least one such principal character-imparting constituent, because a fragrance is formulated around the constituents that produce its characteristic odor. Even if specific identification were required, it would have been obvious to a POSITA that the fragrance includes at least one principal, character-imparting constituent from which its fragrance is obtained. A POSITA formulating or evaluating an encapsulated fragrance would have been motivated to characterize its principal odor-bearing constituents, because those constituents define the product’s commercial value and are the constituents a formulator monitors. And a POSITA would have had a reasonable expectation of success in doing so: identifying the principal character-imparting constituents of a fragrance was routine analytical work (e.g., GC-MS of the type Subramaniam performs to quantify “the various perfuming ingredients,” EX-1004, [0067]), and fragrances would typically have such constituents.

216. At least one constituent “perfuming ingredient” of the Example 5 fragrance is a principal, character-imparting molecular type from which the desirable fragrance is obtained. Accordingly, Subramaniam discloses or at least renders obvious *the initial active ingredient includes one or more constituent components,*

at least one of which is among one or more principle molecular types from which at least one of a desirable fragrance is obtained. EX-1004, [0015], [0060].

[1c] the final active ingredient includes one or more of the constituent components corresponding with those of the initial active ingredient as modified by the drying of the slurry; and

217. Subramaniam discloses that *the final active ingredient* (e.g., the fragrance as recovered from Example 5's spray-dried powder) *includes one or more of the constituent components* (e.g., the fragrance's constituent perfuming ingredients) *corresponding with those of the initial active ingredient* (e.g., the same perfuming ingredients as loaded into Example 5's aqueous emulsion) *as modified by the drying of the slurry.*

218. In Example 5, the spray-dried product is reported to have a fragrance retention of 100% after spray-drying. EX-1004, [0061] (“The final product (after the process) had a flavor retention of 100% (solid content of the emulsion introduced into the spray-drier of 33.98%).”); [1d] below (explaining that the [0061] reference to “flavor retention” should be understood to include “fragrance retention”, consistent with Subramaniam's express reference to “flavor or fragrance retention” (EX-1004, [0047])).

Subramaniam (EX-1004), Example 5 (annotated)		
<u>Example 5</u>		
<u>Preparation of a spray-dried composition according to the invention</u>		
Formulation :		
[0060]		
Ingredients	Grams	% dry
Maltodextrin 18DE	2079	29.70
Sucrose	2079	29.70
Agar agar	700	10.00
Fragrance 1)	2100	30.00
Lecithin	42	0.60
Water	13600	
Total		100.00
1) origin : Firmenich SA, Geneva, Switzerland		
Preparation : The spray-dried powder was prepared as described in Example 1.		
[0061] The final product (after the process) had a flavor retention of 100% (solid content of the emulsion introduced into the spray-drier of 33.98%).		
= carrier (maltodextrin, sucrose, agar agar) = active ingredient (fragrance) = 100% flavor retention of the final product		

219. The 100% recovery reported in Subramaniam [0061] is a *bulk* fragrance retention: Subramaniam reports the Example 5 result as a single percentage for the “Fragrance” as loaded, with no per-constituent breakdown, and a value at the level of the whole fragrance can be 100% only if each of its constituent perfuming ingredients was likewise recovered. A POSITA would have understood that a 100% bulk retention of the fragrance through the spray-drying process indicates that the fragrance recovered from the spray-dried Example 5 powder—the final active ingredient—contains the same constituent perfuming ingredients that were loaded into the aqueous emulsion as the initial active ingredient. A POSITA would have understood that a constituent perfuming ingredient of the fragrance cannot be

selectively lost during spray drying while retaining the bulk fragrance at 100%.

220. Additionally, the *final active ingredient* (fragrance recovered in the spray-dried powder) includes *one or more of the constituent components* corresponding with those of the initial active ingredient *as modified by the drying of the slurry*. Per the '776 specification, the “as modified by the drying of the slurry” limitation encompasses scenarios where the final active ingredient reflects modifications occurring from spray drying (e.g., encapsulation). For example, the specification describes that modifications from drying the slurry include heat-induced modifications occurring during the spray-drying process itself: “The droplets[,] however, do become heated to a point at which considerable portions of desired constituents of the droplets (i.e., portions of the load) are undesirably modified, such as evaporated and/or oxidized. The undesirable modification to the load (load loss) leads to a reduction in flavor (in the case of food loads), a reduction in aroma (in the case of fragrances), etc.” EX-1001, 2:31–37. Here, the specification contemplates modification due to the spray-drying process, and not being limited to a modification in a separate, quantified value in the final active ingredient. *See id.* Congruently, Subramaniam discloses that the final active ingredient in Example 5’s spray-dried powder is the fragrance as modified by the heat induced modification stemming from the spray-drying step that resulted in the fragrance being encapsulated. EX-1004, [0050]-[0051], [0060]-[0061].

221. Accordingly, Subramaniam discloses *the final active ingredient includes one or more of the constituent components corresponding with those of the initial active ingredient as modified by the drying of the slurry*. EX-1004, [0050]-[0051], [0060]-[0061].

[1d] a weight percentage of at least one of the one or more principle molecular types in the final active ingredient is within about 5% of a weight percentage of the corresponding principle molecular types in the initial active ingredient.

222. Subramaniam discloses or renders obvious *a weight percentage of at least one of the one or more principle molecular types* (e.g., at least one principle molecular type of Example 5's fragrance) *in the final active ingredient* (e.g., the fragrance as recovered from Example 5's spray-dried powder) *is within about 5%* (e.g., 0% variation—100% retention) *of a weight percentage of the corresponding principle molecular types in the initial active ingredient* (e.g., the fragrance as loaded into Example 5's spray-drier emulsion at 30% dry weight).

223. Example 5 discloses that preparation of a spray-dried composition containing fragrance (origin: Firmenich SA, Geneva, Switzerland) at 30% dry weight, encapsulated in a maltodextrin/sucrose/agar agar carrier (29.70% maltodextrin 18DE, 29.70% sucrose, and 10.00% agar agar, by dry weight), with 0.60% lecithin as an emulsifier. EX-1004, [0060]-[0061]. This spray-dried powder

is prepared according to Example 1's method, i.e., homogenizing an aqueous emulsion of the foregoing ingredients and spray-drying the emulsion in a Leafash apparatus at 180°C inlet/80°C outlet temperatures. EX-1004, [0050]-[0051], [0060]. Subramaniam reports that "[t]he final product (after the process) had a flavor retention of 100% (solid content of the emulsion introduced into the spray-drier of 33.98%)." EX-1004, [0061].

224. As a starting point, a POSITA would have understood that the phrasing "flavor retention" in paragraph [0061] as to Example 5 is intended to include "fragrance retention." That is because the active ingredient of Example 5 is identified as "Fragrance" (not "flavor") in the composition table at paragraph [0060], and Subramaniam separately uses "flavor retention" only with respect to its lemon-oil examples (Examples 1-4), where the active ingredient is a flavorant. EX-1004, [0052] (Example 1), [0055] (Example 2), [0057] (Example 3), [0059] (Example 4). Examples 1-3 likewise describe the "flavor retention" of "lemon oil." EX-1004, [0049], [0052], [0054]-[0057]; see also EX-1004, [0058]-[0059] (Example 4).

Example 4

Example 4

Preparation of a spray-dried composition according to the invention

Formulation :

[0058]

Ingredients	Grams	%dry
Maltodextrin 18DE	798	11.40
Sucrose	1554	22.20
Agar agar	1050	15.00
Gum Arabic	798	11.40
Lemon oil ¹⁾	2800	40.00
Water	18200	
Total		100.00
1) see Example 1		

Preparation : The spray-dried powder was prepared as described in Example 1.

[0059] The final product (after the process) had a flavor retention of 87.00% (solid content of the emulsion introduced into the spray-drier of 27.78%).

Example 5

Example 5

Preparation of a spray-dried composition according to the invention

Formulation :

[0060]

Ingredients	Grams	% dry
Maltodextrin 18DE	2079	29.70
Sucrose	2079	29.70
Agar agar	700	10.00
Fragrance ¹⁾	2100	30.00
Lecithin	42	0.60
Water	13600	
Total		100.00
1) origin : Firmenich SA, Geneva, Switzerland		

Preparation : The spray-dried powder was prepared as described in Example 1.

[0061] The final product (after the process) had a flavor retention of 100% (solid content of the emulsion introduced into the spray-drier of 33.98%).

225. Moreover, Subramaniam's general teaching at paragraph [0047] confirms both the dual usage of "flavor or fragrance retention" and the meaning of

“retention” as the proportion of active ingredient recovered in the spray-dried product: “the compositions of the invention provide a flavor or fragrance retention of up to 85% after the encapsulation process.” EX-1004, [0047].

226. Because Example 5 discloses that its spray-drying process results in 100% bulk retention of the fragrance (i.e., the final active ingredient) (EX-1004, [0061]), a recovery at or near 100% means little or no constituent was lost (as spray drying does not create any constituent components not already present). Additionally, since the principal, character-imparting constituents make up most of the fragrance, a POSITA would have understood or found obvious that those constituents were recovered substantially intact. A reported recovery at/near 100% leaves the “share” of the principal constituents substantially unchanged. It follows that the weight percentage of at least one component within Subramaniam’s recovered fragrance is within about 5% of its weight percentage in the initial fragrance.

227. Accordingly, Subramaniam discloses *a weight percentage of at least one of the one or more principle molecular types in the final active ingredient is within about 5% of a weight percentage of the corresponding principle molecular types in the initial active ingredient*. EX-1004, [0047], [0050]-[0051], [0060]-[0061].

Dependent Claim 2

[2] The spray dried powder of claim 1, wherein the one or more principle molecular types are molecular types of a food composition.

228. Subramaniam discloses or renders obvious that *the one or more principle molecular types* (e.g., at least one perfuming ingredient of Example 5's fragrance from which the fragrance is obtained) are molecular types *of a food composition* (e.g., used for the perfuming or flavoring food compositions).

229. Subramaniam teaches that its spray-dried "active ingredient" (here, fragrance) "may include volatile perfuming or flavoring ingredients, as well as other kinds of ingredients such as pharmaceutical actives" (EX-1004, [0015]) and that the spray-dried products "can be advantageously used ... for the perfuming or flavoring of food compositions" including "chewing gums or chewing sweets, savoury food or baking in the field of flavours" (EX-1004, [0044]-[0045]). [1b] above; *see also* EX-1001, 12:19–30, 15:18–24, 18:13–18, FIG. 11 (similarly explaining that the same molecular type can be of a food or flavor composition, depending on end use; treating orange oil's D-limonene as simultaneously a flavor and a food principle molecular type). Accordingly, a POSITA would have understood that at least one perfuming ingredient of Example 5's fragrance (i.e., *one or more principle molecular types*) is a *molecular type of a food composition*.

Dependent Claim 3

[3] The spray dried powder of claim 1, wherein the one or more principle molecular types are molecular types of a flavor composition.

230. Subramaniam discloses or renders obvious that *the one or more principle molecular types* (e.g., at least one perfuming ingredient of Example 5's fragrance from which the fragrance is obtained) are molecular types *of a flavor composition* (e.g., used for the flavoring food compositions).

231. Subramaniam's spray-dried "active ingredient" (here, fragrance) "may include volatile perfuming or flavoring ingredients" (EX-1004, [0015]), and the invention's second object is "the flavoring or perfuming of consumer products such as foods, beverages, or perfuming compositions" (EX-1004, [0017]). Subramaniam's Examples 1-4 prepare spray-dried compositions where lemon oil—a flavor—is the active ingredient. EX-1004, [0049]-[0059]; [1b] above. *See also* EX-1001, 12:19–30, 15:18–24, 18:13–18, FIG. 11 (similarly explaining that the same molecular type can be of a food or flavor composition, depending on end use; treating orange oil's D-limonene as simultaneously a flavor and a food principle molecular type). Accordingly, a POSITA would have understood that at least one perfuming ingredient of Example 5's fragrance (i.e., *one or more principle molecular types*)—a principle molecular type from which the active ingredient's fragrance/perfuming property is obtained, and which is present in a powder that

Subramaniam teaches is used for “the flavoring ... of consumer products such as foods” (EX-1004, [0017])—is itself a *molecular type of a flavor composition*.

Dependent Claim 4

[4] The spray dried powder of claim 1, wherein the one or more principle molecular types are molecular types of a fragrance composition.

232. Subramaniam discloses or renders obvious that *the one or more principle molecular types* (e.g., at least one perfuming ingredient of Example 5’s fragrance from which the fragrance is obtained) are molecular types *of a fragrance composition* (e.g., used for perfuming a product).

233. Example 5’s active ingredient is “Fragrance” (origin: Firmenich SA, Geneva, Switzerland), present at 30% dry weight. EX-1004, [0060]; [1b] above. A fragrance is, by definition, a perfuming composition the constituent perfuming ingredients of which are principle molecular types of the fragrance. *See* EX-1032 (Pybus). Accordingly, a POSITA would have understood that at least one perfuming ingredient of Example 5’s fragrance (i.e., *one or more principle molecular types*)—being a constituent from which the active ingredient’s fragrance/perfuming property is obtained, and which is present in a powder that Subramaniam teaches “may include volatile perfuming ... ingredients” and is used for the perfuming of a product (EX-1004, [0015], [0017])—is itself a *molecular type of a fragrance composition*.

Dependent Claim 5

[5] The spray dried powder of claim 1, wherein the one or more principle molecular types are molecular types of a medicament composition.

234. Subramaniam discloses or renders obvious that *the one or more principle molecular types* (e.g., at least one pharmaceutical active Subramaniam teaches its spray-dried active ingredient may include, from which the medical/therapeutic effect is obtained) is a molecular type *of a medicament composition* (e.g., used as/in a medicament).

235. Subramaniam teaches that its spray-dried composition's active ingredient "may include ... pharmaceutical actives." EX-1004, [0015]; [1b] above. Accordingly, a POSITA would have understood that at least one such pharmaceutical active included in Subramaniam's spray-dried active ingredient (i.e., *one or more principle molecular types*) — being a constituent from which the active ingredient's medical/therapeutic property is obtained, and which is present in a powder that may be used as or in a medicament — is itself a *molecular type of a medicament composition*.

Dependent Claim 7

[7] The spray dried powder of claim 1, wherein the weight percentage of at least one of the one or more principle molecular types in the final active

ingredient is within about 3% of a weight percentage of the corresponding principle molecular types in the initial active ingredient.

236. Subramaniam discloses claim 7 for the reasons in [1d] above. As explained above in [1d], Subramaniam's spray drying process results in a 100% bulk retention of the spray-dried powder's fragrance. Thus, a POSITA would have understood that the weight percentage of the fragrance's perfuming ingredients (i.e., *the at least one of the one or more principle molecular types in the final active ingredient*) has 0% variance relative to the same ingredients in the fragrance before spray drying—and thereby, *is within about 3% of a weight percentage of the corresponding principle molecular types in the initial active ingredient.*

Dependent Claim 8

[8] The spray dried powder of claim 1, wherein the weight percentage of at least one of the one or more principle molecular types in the final active ingredient is within about 2% of a weight percentage of the corresponding principle molecular types in the initial active ingredient.

237. Subramaniam discloses claim 8 for the reasons in [1d] above. As explained above in [1d], Subramaniam's spray drying process results in a 100% bulk retention of the spray-dried powder's fragrance. Thus, a POSITA would have understood that the weight percentage of the fragrance's perfuming ingredients (i.e.,

the at least one of the one or more principle molecular types in the final active ingredient) has 0% variance relative to the same ingredients in the fragrance before spray drying—and thereby, *is within about 2% of a weight percentage of the corresponding principle molecular types in the initial active ingredient.*

Dependent Claim 9

[9] The spray dried powder of claim 1, wherein the weight percentage of at least one of the one or more principle molecular types in the final active ingredient is within about 1% of a weight percentage of the corresponding principle molecular types in the initial active ingredient.

238. Subramaniam discloses claim 9 for the reasons in [1d] above. As explained above in [1d], Subramaniam's spray drying process results in a 100% bulk retention of the spray-dried powder's fragrance. Thus, a POSITA would have understood that the weight percentage of the fragrance's perfuming ingredients (i.e., *the at least one of the one or more principle molecular types in the final active ingredient)* has 0% variance relative to the same ingredients in the fragrance before spray drying—and thereby, *is within about 1% of a weight percentage of the corresponding principle molecular types in the initial active ingredient.*

Independent Claim 10

[10pre] A spray dried powder, comprising:

239. If the preamble is limiting, Subramaniam discloses *a spray-dried powder* (e.g., spray-dried powder described in the context of Example 7's Formulation A). Example 7's Formulation A is similar to that of Example 5 because, as explained in [1pre] above, it was "prepared according to the method described in Example 1." EX-1004, [0001], [0004]-[0005], [0014], [0016], [0020], [0048], [0050]-[0051], [0064]-[0065].

[10a] a plurality of dried particles, which individually contain an amount of active ingredient encapsulated within a carrier, wherein:

240. Subramaniam discloses *a plurality of dried particles* (e.g., Formulation A's spray-dried particulates) *which individually contain an amount of active ingredient* (e.g., Formulation A's perfume composition) *encapsulated within a carrier* (e.g., a maltodextrin/sucrose/agar agar carrier).

241. Subramaniam discloses *a plurality of dried particles* (e.g., Formulation A's spray-dried particulates). In Example 7, Formulation A's aqueous emulsion is prepared by combining maltodextrin 18DE, sucrose, perfume composition, agar agar, lecithin, and water. EX-1004, [0065].

Subramaniam (EX-1004), Example 7 (annotated)

Example 7

Comparative example on the stability of a spray-dried composition according to the invention, in a detergent base

[0064] Two spray-dried compositions having the following formulations were prepared according to the method described in Example 1 :

Formulation A :

[0065]

Ingredients	Grams	% dry
Maltodextrin 18DE	2865	38.20
Sucrose	2865	38.20
Perfume composition 1)	1500	20.00
Agar agar	225	3.00
Lecithin	45	0.60
Water Total	9600	100.00

1) composition consisting of a mixture of benzyl acetate, phenylethyl acetate, cyclamen aldehyde, Lilial® (origin: Givaudan-Roure, Vernier, Switzerland) and hexyl salicylate ; each ingredient being present in the same weight percentage in the composition

 = carrier (maltodextrin, sucrose, agar agar)

 = active ingredient (perfume composition)

242. Subramaniam explains that Example 1's method is used to prepare Example 7's Formulation A, which involves preparing the emulsion by "hydrating agar agar in water" and "subsequently mixing it with the rest of the ingredients." EX-1004, [0050]; [0064]. The aqueous emulsion is then spray dried, producing dried particles. EX-1004, [0005], [0051], [0064].

243. Subramaniam discloses that Formulation A's spray-dried particulates *individually contain an amount of active ingredient* (e.g., Formulation A's perfume composition). The perfume composition is the active ingredient. EX-1004, [0031]

(“The active ingredient dispersed in the carrier of the spray-dried composition of the invention will preferably be a hydrophobic flavor or fragrance ingredient or composition of current use.”), [0015] (“What is meant here by ‘active ingredient’, is a liquid ingredient, preferably hydrophobic, which is sought to be protected by way of solid encapsulation. It may include volatile perfuming or flavoring ingredients, as well as other kinds of ingredients such as pharmaceutical actives for instance.”), [0065], [0067].

244. Formulation A’s spray-dried particulates (EX-1004, [0051], [0064]) that individually contain an amount of the perfume composition (*active ingredient*) are *encapsulated within a carrier* (e.g., a maltodextrin/sucrose/agar agar carrier). EX-1004, [0005], [0053], [0065]. Subramaniam teaches that, “[i]n spray-dried powders, an active ingredient such as a flavor or a fragrance, usually hydrophobic, is entrapped as liquid droplets in a solidified matrix of a dehydrated carrier, generally consisting of carbohydrates, such as starches, hydrolyzed starches (maltodextrin), chemically modified starches, emulsifying polymers (gum arabic) and in certain instances monomers and dimers of simple aldohexoses, or any combination thereof.” EX-1004, [0005]. The carrier of the resulting dried particles comprises wall-forming carbohydrate materials (maltodextrin, sucrose) together with agar agar, per Subramaniam’s general teaching at [0020]. EX-1004, [0020], [0065].

Subramaniam (EX-1004), Example 7 (annotated)

Example 7

Comparative example on the stability of a spray-dried composition according to the invention, in a detergent base

[0064] Two spray-dried compositions having the following formulations were prepared according to the method described in Example 1 :

Formulation A :

[0065]

Ingredients	Grams	% dry
Maltodextrin 18DE	2865	38.20
Sucrose	2865	38.20
Perfume composition 1)	1500	20.00
Agar agar	225	3.00
Lecithin	45	0.60
Water Total	9600	100.00

1) composition consisting of a mixture of benzyl acetate, phenylethyl acetate, cyclamen aldehyde, Lilial® (origin: Givaudan-Roure, Vernier, Switzerland) and hexyl salicylate ; each ingredient being present in the same weight percentage in the composition

 = carrier (maltodextrin, sucrose, agar agar)

 = active ingredient (perfume composition)

245. Accordingly, Subramaniam discloses *a plurality of dried particles, which individually contain an amount of active ingredient encapsulated within a carrier*. EX-1004, [0005], [0020], [0050]-[0053], [0064]-[0065].

[10b] the active ingredient includes one or more constituent components, at least one of which is among one or more principle molecular types from which

at least one of a desirable food, flavor, fragrance, medicament, and pigment is obtained; and

246. Subramaniam discloses that *the active ingredient* (e.g., Formulation A's perfume composition) *includes one or more constituent components* (e.g., benzyl acetate, phenylethyl acetate, cyclamen aldehyde, Lilial®, and hexyl salicylate), *at least one of which is among one or more principle molecular types from which at least one of a desirable fragrance is obtained* (e.g., the desirable scent of Formulation A's perfume composition).

247. Formulation A's *active ingredient*—the perfume composition—includes the following *constituent components*: “a mixture of benzyl acetate, phenylethyl acetate, cyclamen aldehyde, Lilial® (origin: Givaudan-Roure, Vernier, Switzerland) and hexyl salicylate; each ingredient being present in the same weight percentage in the composition.” EX-1004, [0065], n.1.

Subramaniam (EX-1004), Example 7 (annotated)

Example 7

Comparative example on the stability of a spray-dried composition according to the invention, in a detergent base

[0064] Two spray-dried compositions having the following formulations were prepared according to the method described in Example 1 :

Formulation A :

[0065]

Ingredients	Grams	% dry
Maltodextrin 18DE	2865	38.20
Sucrose	2865	38.20
Perfume composition ¹⁾	1500	20.00
Agar agar	225	3.00
Lecithin	45	0.60
Water Total	9600	100.00
1) composition consisting of a mixture of benzyl acetate, phenylethyl acetate, cyclamen aldehyde, Lilial® (origin: Givaudan-Roure, Vernier, Switzerland) and hexyl salicylate ; each ingredient being present in the same weight percentage in the composition		

- = carrier (maltodextrin, sucrose, agar agar)
 = active ingredient (perfume composition)
 = constituent components (footnote 1)

248. Each constituent component is a perfuming ingredient from which the fragrance of Formulation A's perfume composition is obtained. EX-1004, [0065], n.1, [0067]-[0068], Table 1. Subramaniam refers to Example 7's constituent components as "perfuming ingredients." EX-1004, [0067] (describing GC-MS analysis "to determine the residual quantity of the various perfuming ingredients"); EX-1004, [0068] (referring to "the highest proportion of perfuming ingredients which have not been decomposed"); EX-1004, Table 1 (titled "Percentage of perfume ingredients recovered").

249. Each constituent component (benzyl acetate, phenylethyl acetate, cyclamen aldehyde, Lilial®, and hexyl salicylate) is a ***principle molecular type from which the desirable fragrance*** (fragrance of Formulation A’s perfume composition) ***is obtained***. As explained above, per the ’776 patent, a “principle molecular type” from which a characteristic (here, fragrance/scent) of the active ingredient is obtained encompasses a constituent component that ultimately contributes to the desired characteristic (here, scent), such that when the component’s concentration decreases in the overall spray-dried composition, the desired characteristic (here, scent) is likewise undesirably altered. EX-1001, 2:31–37. Here, each of the five perfume composition’s constituent components are “perfuming ingredients”—each present in the “same weight percentages”—contributing to the desirable fragrance. EX-1004, [0065], n.1, [0067]–[0068], Table 1. The claim’s “one or more”/“at least one of” language confirms that the perfume composition may have multiple principle molecular types simultaneously and is not limited to the single most abundant/dominant constituent. EX-1001, 17:66–18:1, 18:8 (claim 1); *see also id.* at 18:47–52 (claim 10), 20:7–21 (claim 20), 18:19–21 (claim 4), 18:63–65 (claim 13).

250. Accordingly, Subramaniam discloses ***the active ingredient includes one or more constituent components, at least one of which is among one or more principle molecular types from which at least one of a desirable fragrance is obtained***. EX-1004, [0015], [0065], n.1, [0067]–[0068], Table 1.

[10c] a weight percentage of at least one of the one or more principle molecular types in the active ingredient does not vary by more than about 5% during aging of the dried powder during any period of elevated temperature of about 95°F up to about 1000 hours.

251. Subramaniam discloses or renders obvious *a weight percentage of at least one of the one or more principle molecular types* (e.g., hexyl salicylate) *in the active ingredient* (e.g., Formulation A's perfume composition) *does not vary by more than about 5% during aging of the dried powder* (e.g., 0% variation—100% recovery) *during any period of elevated temperature of about 95°F up to about 1000 hours.*

252. As a threshold matter, this limitation encompasses stability over time—whether a principle molecular type's weight percentage in the active ingredient changes during aging relative to its weight before aging. EX-1001, claim 10. The '776 specification confirms this, describing the allegedly inventive property as a principle molecular type that “does not vary significantly ... during aging of the dried powder” at the recited temperature and duration. EX-1001, 2:31–40. This is a before-and-after comparison of the same molecule across aging, not a comparison of one constituent's “share” against the others. Congruently, Subramaniam discloses or renders obvious the instant limitation.

253. As explained above, Example 7 prepares a spray-dried powder (“Formulation A”) containing a perfume composition of benzyl acetate, phenylethyl acetate, cyclamen aldehyde, Lilial®, and hexyl salicylate, encapsulated in a maltodextrin/sucrose/agar agar carrier. EX-1004, [0064]-[0065]. Each perfuming ingredient is a *principle molecular type from which a desirable fragrance is obtained*, as explained in [10b]. EX-1004, [0064]; [10b] above.

254. Subramaniam discloses that the weight percentage of hexyl salicylate, one of *the principle molecular types in the active ingredient* (e.g., Formulation A’s perfume composition) *did not vary by more than about 5% during aging of the dried powder*. In Example 7, Subramaniam admixed the Formulation A powder with a standard European detergent containing a percarbonate-TAED bleaching system, stored the mixture for four weeks at 37°C and 70% relative humidity, then separated the powder from the detergent and quantified the residual perfuming ingredients by GC-MS. EX-1004, [0067]. Table 1 (reproduced below) reports the percentage of each perfuming ingredient recovered after this storage period relative to the amount of each perfuming ingredient incorporated into the composition. EX-1004, [0067], Table 1. Subramaniam separately reports, as a comparative control, a reference detergent onto which the pure perfume composition was sprayed directly and stored at 3°C. EX-1004, [0067], Table 1.

Subramaniam (EX-1004), Example 7 — Table 1 (annotated)

Table 1 : Percentage of perfume ingredients recovered after storage for four weeks at 37° and 70% RH

Perfuming ingredient	Sprayed-on detergent powder	Formulation B (no agar agar)	Formulation A (3% of agar agar)
Benzyl acetate	3	6	6
Phenyl ethyl acetate	10	18	23
Cyclamen aldehyde	31	45	67
Lilial®	0.0	2	10
Hexyl salicylate	25	48	100

■ = perfuming ingredient (active ingredient)

■ = hexyl salicylate (constituent component) / 100% recovery

■ = Formulation A (3% agar agar)

255. For hexyl salicylate in Formulation A, Table 1 lists a 100% recovery. EX-1004, Table 1 (annotated). A POSITA would have understood that 100% recovery indicates a 0% weight variation of hexyl salicylate before and after the aging, which is within the claimed weight percentage variance of *no more than about 5% during aging*.

256. Subramaniam discloses that the weight percentage of hexyl salicylate did not vary by more than 5% *during aging of the dried powder* during any period of *elevated temperature of about 95°F* up to about 1000 hours. Formulation A was stored at an elevated temperature of 37°C/98.6°F, which is about (and in excess of) 95°F as recited in the claim. EX-1004, [0067], Table 1. Moreover, because degradation slows as temperature falls, an ingredient retained at 37°C would be retained at least as well at 95°F. EX-1007 at 14–15, 19, Fig. 1.9.

257. Further, Subramaniam discloses or renders obvious that the weight percentage of hexyl salicylate did not vary by more than 5% *during any period* of

elevated temperature of about 95°F *up to about 1000 hours* for the reasons noted below.

258. If the claim limitation “during any period ... up to about 1000 hours” is interpreted as setting a minimum duration of about 1000 hours for the aging, [10c] would have been obvious to a POSITA in view of Subramaniam and the well-known principles of accelerated stability testing. As explained below, a POSITA, reading Subramaniam’s Example 7 and the reported 100% recovery of hexyl salicylate after four weeks at 37°C / 70% relative humidity in a percarbonate-TAED detergent, would have found it obvious that hexyl salicylate would satisfy the milder *elevated temperature of about 95°F* test of [10c] over a period of about 1000 hours with a reasonable expectation of success. EX-1004, [0067], Table 1.

259. First, Subramaniam subjected hexyl salicylate to materially more stressful storage conditions than [10c] specifies, on three independent axes: higher temperature, added humidity, and a harsher bleach-testing environment.

260. Subramaniam’s storage temperature is higher than [10c] requires. Subramaniam stored Formulation A at 37°C (98.6°F), which exceeds the *elevated temperature of about 95°F* recited in [10c]. A POSITA would have understood that the rate of chemical degradation increases with temperature, so an ingredient retained at 37°C would be retained at least as well at about 35°C (95°F) over an equal or longer period. Singh (EX-1007), at 14–15, 19, Fig. 1.9; FDA Q1A(R2) (EX-

1009), §§ 1.3, 2.1.2; ICH Q1A(R2) (EX-1008), §§ 2.1.7, 2.2.7.

261. Subramaniam also adds elevated humidity that the [10c] aging limitation does not require. Subramaniam stored Formulation A at 70% relative humidity, whereas the [10c] test specifies no humidity condition and the '776 specification only disclosed embodiment is a dry hot box (which would not be subject to any humidity). EX-1001, 14:21-40. A POSITA would have understood that 70% relative humidity accelerates degradation of a dried powder relative to that dry baseline, making the moisture present in Subramaniam an additional stressor absent from the [10c] test. ICH Q1A(R2) (EX-1008), §§ 2.1.7, 2.2.7; FDA Q1A(R2) (EX-1009), §§ 2.1.2, 2.1.7, 2.2.7.

262. Subramaniam further adds an active chemical oxidant that the [10c] aging limitation does not require. Subramaniam admixes the encapsulated powder with a detergent containing a percarbonate-TAED bleaching system—an environment understood to generate peracetic acid, a strong oxidant capable of degrading fragrance materials, and one the industry used as a standardized accelerated bleach-stability screen precisely because of its severity. Hagemann (EX-1010); *see also* EX-1001, 14:21-40 (the described aging in the '776 specification presented only a thermal stress, with no chemical oxidant present).

263. Each of these conditions is a significant stressor and resulted in degradation of certain components, e.g., benzyl acetate fell to 6%, phenyl ethyl

acetate to 23%, cyclamen aldehyde to 67%, and Lilial® to 10%. EX-1004, Table 1. However, under the identical Example 7 conditions, hexyl salicylate in Formulation A was recovered at 100% (a 0% variation). *See id.* That hexyl salicylate showed no degradation despite these stressors demonstrates that it would also show no degradation in a milder environment that is broadly encompassed by the claim—i.e., one without humidity, lower temperature, and without a chemical oxidant.

264. Subramaniam aged Formulation A for 672 hours; [10c] recites a period up to about 1,000 hours. EX-1004, [0067]. If [10c] requires aging for about 1000 hours, that limitation would have been obvious (for reasons similar to those noted above in the Watanabe ground; *see* Section X.B, IV.B.4.[10c]). A POSITA evaluating an encapsulated fragrance would have wanted to confirm stability across a commercial shelf life on the order of 1,000 hours, because retention over that period determines whether the product remains usable. Projecting a shorter stability (e.g., the 672 hours of testing in Subramaniam) result to a longer period (e.g., 1000 hours as recited in the claim) is the conventional and ordinary purpose of accelerated testing. EX-1007 at 14-19. A POSITA would have expected hexyl salicylate to stay within about 5% at 1,000 hours. That is because a POSITA would have reasonably expected hexyl salicylate, having survived the harsher test intact, to remain well within [10c]’s ***about 5%*** threshold across the milder conditions the claim encompasses and for a longer duration than the 672 hours of aging in Subramaniam’s

Example 7.

265. Arrhenius or Q10 modeling is neither necessary nor available to establish the stability of hexyl salicylate under the conditions of claim 10. Subramaniam tested hexyl salicylate under conditions more severe than the claim on every specified axis: a higher temperature (37°C versus the claim's approximately 95°F, i.e., about 35°C), an added oxidative bleaching system (percarbonate-TAED), and elevated humidity (70% RH). Neither the oxidant nor the elevated humidity is required by claim 10 or present in the dry-oven test described in the specification. EX-1004, [0067]; EX-1001, claim 10. Even under these harsher conditions, Subramaniam reported 100% recovery of hexyl salicylate, that is, no measurable degradation. EX-1004, Table 1. Because each of these stressors either accelerates degradation or is absent under the milder claimed condition, a POSITA would have reasonably expected hexyl salicylate to exhibit no greater loss, and thus to remain within the about 5% variance, over the claimed period. Arrhenius and Q10 modeling do not alter this result and cannot be performed here in any event: those tools scale a measured, nonzero degradation rate to a different temperature or time, and Subramaniam's single endpoint reports a degradation rate of zero, leaving nothing to scale. Scaling zero by any temperature factor over any duration yields zero.

266. The unavailability of Arrhenius and Q₁₀ modeling here rests on more than the zero measured rate. A valid Arrhenius or Q₁₀ projection requires degradation

rate constants for the same formulation and the same degradation mechanism, measured at two or more temperatures, from which the temperature dependence (the activation energy, or Q_{10}) is derived. Example 7 supplies a single recovery value, for a single formulation, at a single temperature and a single time point. Compounding this, Example 7's storage environment—an encapsulated powder admixed with a percarbonate-TAED bleaching detergent at 70% relative humidity—drives several degradation pathways in parallel (oxidation, hydrolysis, moisture uptake, and diffusion) that do not share a single activation energy, so there is no single Arrhenius-governed reaction whose rate could be scaled with temperature. EX-1008 (ICH Q1A(R2)); EX-1009 (FDA Q1A(R2)); EX-1007 (Singh).

267. The 3°C sprayed-on reference does not supply the missing second temperature. That reference is a different, unencapsulated sample—the pure perfume composition sprayed directly onto detergent—not the encapsulated Formulation A powder held at a second temperature. It therefore cannot provide the second same-formulation, same-mechanism rate constant that an Arrhenius analysis requires. EX-1004, [0067], Table 1.

268. Even a valid activation energy would still require a measured, nonzero degradation rate to scale, and Example 7's 100% recovery of hexyl salicylate supplies none. Nor could a literature activation energy be substituted: no activation energy was identified for hexyl salicylate in this formulation and this percarbonate-

TAED, elevated-humidity exposure system, and activation energies drawn from other matrices, other degradation mechanisms, or other salicylate analogues are not kinetically transferable to this system without validation.

269. For the same reasons, a linear regression cannot be performed on the Example 7 data. A regression requires multiple independent time points to estimate a rate (the slope) and its uncertainty; Example 7 provides one storage endpoint, with no documented time-zero assay and no measure of variability. Pairing that single endpoint with an assumed 100% at time zero yields a two-point line, not a regression—there are no residual degrees of freedom, no confidence interval, and no evidence that the underlying kinetics are linear. And because both the assumed time-zero value and the measured four-week value are 100%, that two-point line has a slope of zero: there is no degradation rate from which to extrapolate at all.

270. As an illustrative bounding exercise, a deliberately conservative linear extrapolation treatment confirms that hexyl salicylate would remain within the threshold of [10c] at about 1000 hours. A linear framework is a straight-line model of how an ingredient is lost over time: it assumes the ingredient is consumed at a constant rate, so the percentage retained falls along a straight line from 100% at the start of the test. Such a model is used to bridge the gap between the point at which stability was actually measured and the longer period the claim describes—here, from Subramaniam’s four-week (672-hour) measurement to the 1000-hour period as

allegedly required by the claim. Because Subramaniam provides a single storage endpoint, this straight-line treatment is not a regression and is not presented as establishing the actual degradation kinetics of Formulation A; it serves only to bound the result.

271. Applying that linear framework here proceeds in three steps. The claim first sets the target: a variation of no more than **about 5%** means retention must stay at or above 95% through about 1000 hours. Next, the worst case the claim allows is identified—i.e., the fastest straight-line decline that just reaches 95% at exactly 1000 hours, which is a loss of five percentage points spread over 1000 hours, or 0.005% per hour. Finally, it is evaluated whether that line would sit at 672 hours, the point Subramaniam actually measured: losing 0.005% per hour for 672 hours is a 3.36% loss, leaving 96.64% retained. The lesson is that any ingredient still on track to satisfy the claim at 1000 hours must show at least 96.64% retention at 672 hours. Subramaniam's hexyl salicylate was at 100% at 672 hours—well above that 96.64% floor—so it is declining more slowly than the worst case and, under the same linear framework, stays within the **about 5%** band at 1000 hours. The same framework applied to stricter targets tells the same story: to finish at 99%, 98%, 97%, or 95% at 1000 hours, an ingredient would need to be at 99.33%, 98.66%, 97.98%, or 96.64%, respectively, at 672 hours, and here too, Subramaniam's observed 100% exceeds every one of those values. And because hexyl salicylate in fact showed

100% at 672 hours—no measured loss at all—the linear extrapolation projects 100% through 1000 hours.

272. For completeness, the assumptions and arithmetic underlying that bounding exercise are set out here. The exercise assumes that (i) hexyl salicylate is exactly 100.00% at time zero; (ii) retention declines linearly from time zero through 1,000 hours; (iii) the storage environment is unchanged over the full period; and (iv) four weeks equals 672 hours. Consistent with its deliberately conservative character, the exercise is evaluated at Example 7's own 37°C / 70% relative humidity / percarbonate-TAED condition and takes no credit for the milder about 95°F (35°C) claim temperature. Under those assumptions, the four-week (672-hour) retention required to remain on track for a given 1,000-hour target R_{1000} is $R_{672} = 100 + (R_{1000} - 100) \times (672/1,000)$, which gives:

Desired retention at 1,000 h	Required retention at 672 h	Maximum loss by 672 h
99%	99.33%	0.672%
98%	98.66%	1.344%
97%	97.98%	2.016%
95%	96.64%	3.360%

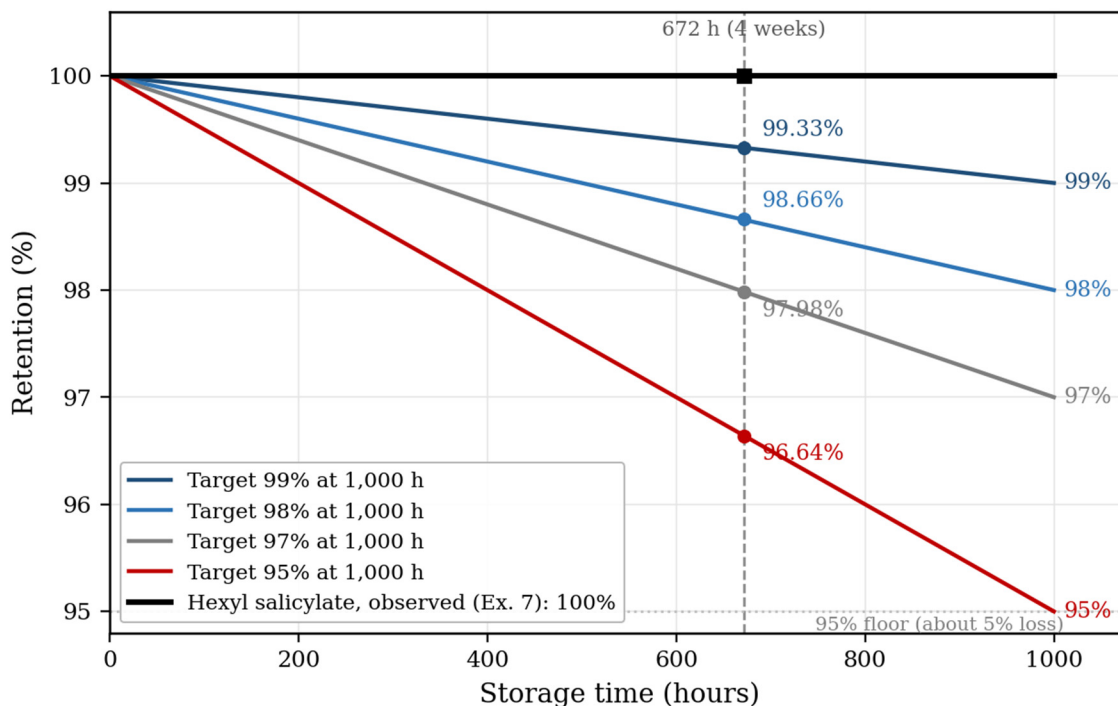


Figure 1. Hypothetical linear retention paths from 100% at time zero to selected target values at 1,000 hours. The markers at 672 hours (four weeks) show the minimum four-week retention required under the assumed linear model; the observed Example 7 value for hexyl salicylate (100%) lies above every such path.

273. Subramaniam’s reported hexyl salicylate value of 100% at 672 hours exceeds every required four-week value in the table—indeed exceeds each even when the 1,000-hour targets are rounded to whole percents—so under the same linear model hexyl salicylate remains within [10c]’s about 5% band, and in fact projects to 100%, through 1,000 hours. As explained above, this is a bounding exercise only; it is not a regression and does not purport to establish Formulation A’s actual degradation kinetics.

274. Taken together, Subramaniam subjected hexyl salicylate to greater stress on every condition than what is broadly required by the claim and observed

no degradation, supporting a reasonable expectation that the same ingredient would satisfy [10c]’s threshold over the claim’s longer, milder test.

275. In the alternative, if “during any period ... up to about 1000 hours” sets the maximum length of the aging period rather than a minimum, Subramaniam discloses [10c] outright. Subramaniam’s hexyl salicylate’s weight percentage did not vary by more than about 5% across the 672 hours of testing imposed by Subramaniam.

276. Accordingly, Subramaniam discloses or renders obvious *a weight percentage of at least one of the one or more principle molecular types* (hexyl salicylate) *in the active ingredient does not vary by more than about 5% during aging of the dried powder during any period of elevated temperature of about 95°F up to about 1000 hours*. EX-1004, [0064]-[0067], Table 1.

Dependent Claim 11

[11] The spray dried powder of claim 10, wherein the one or more principle molecular types are molecular types of a food composition.

277. Subramaniam discloses or renders obvious that *the one or more principle molecular types* (benzyl acetate, phenylethyl acetate, cyclamen aldehyde, Lilial®, and hexyl salicylate of Formulation A’s perfume composition from which a fragrance is obtained) are molecular types *of a food composition* (e.g., used for

perfuming or flavoring food compositions).

278. Subramaniam teaches that its spray-dried “active ingredient” (here, fragrance) “may include volatile perfuming or flavoring ingredients, as well as other kinds of ingredients such as pharmaceutical actives” (EX-1004, [0015]) and that the spray-dried products “can be advantageously used ... for the perfuming or flavoring of food compositions” including “chewing gums or chewing sweets, savoury food or baking in the field of flavours” (EX-1004, [0044]-[0045]). [1b] above. This ’776 patent likewise contemplates that the same molecular type can be that of a food or flavor composition, depending on end use. EX-1001, 12:19–30, 12:43–45, 15:18–24, 18:13–18, FIG. 11 (treating orange oil’s D-limonene as simultaneously a flavor and a food principle molecular type). Accordingly, a POSITA would have understood that at least one of Formulation A’s named perfuming ingredients (i.e., *one or more principle molecular types*) — being a constituent from which the active ingredient’s fragrance/perfuming is obtained, and which is present in a powder that Subramaniam teaches is “advantageously used ... for the perfuming or flavoring of food compositions” — is itself a *molecular type of a food composition*.

Dependent Claim 12

[12] The spray dried powder of claim 10, wherein the one or more principle molecular types are molecular types of a flavor composition.

279. Subramaniam discloses or renders obvious that *the one or more*

principle molecular types (benzyl acetate, phenylethyl acetate, cyclamen aldehyde, Lilial®, and hexyl salicylate of Formulation A’s perfume composition from which the fragrance is obtained) are molecular types *of a flavor composition* (e.g., used for flavoring food compositions).

280. Subramaniam’s spray-dried “active ingredient” (here, fragrance) “may include volatile perfuming or flavoring ingredients” (EX-1004, [0015]), and the invention’s second object is “the flavoring or perfuming of consumer products such as foods, beverages, or perfuming compositions” EX-1004, [0017]. *See also* EX-1001, 12:19–30, 15:18–24, 18:13–18, FIG. 11 (similarly explaining that the same molecular type can be of a food or flavor composition, depending on end use; treating orange oil’s D-limonene as simultaneously a flavor and a food principle molecular type). Accordingly, a POSITA would have understood that at least one of Formulation A’s named perfuming ingredients (i.e., *one or more principle molecular types*) — a principle molecular type from which the active ingredient’s fragrance/perfuming is obtained, and which is present in a powder that Subramaniam teaches is used for “the flavoring ... of consumer products such as foods” (EX-1004, [0017]) — is itself a *molecular type of a flavor composition*.

Dependent Claim 13

[13] The spray dried powder of claim 10, wherein the one or more principle molecular types are molecular types of a fragrance composition.

281. Subramaniam discloses or renders obvious that *the one or more principle molecular types* (benzyl acetate, phenylethyl acetate, cyclamen aldehyde, Lilial®, and hexyl salicylate of Formulation A’s perfume composition from which the fragrance is obtained) are molecular types *of a fragrance composition* (e.g., used for perfuming a product).

282. The active ingredient of Example 7’s Formulation A is a “[p]erfume composition” consisting of five perfuming ingredients (benzyl acetate, phenylethyl acetate, cyclamen aldehyde, Lilial®, and hexyl salicylate). EX-1004, [0065], n.1, [0067]-[0068], Table 1; [10b] above. As explained in [10b] above, each of those five perfuming ingredients is a principle molecular type of the perfume composition—a fragrance composition. Accordingly, a POSITA would have thus understood that at least one of Formulation A’s five perfuming ingredients (i.e., *one or more principle molecular types*) — being a constituent from which the active ingredient’s fragrance/perfuming is obtained — is itself a *molecular type of a fragrance composition*.

Dependent Claim 14

[14] The spray dried powder of claim 10, wherein the one or more principle molecular types are molecular types of a medicament composition.

283. Subramaniam discloses or renders obvious that *the one or more principle molecular types* (at least one of the pharmaceutical actives Subramaniam teaches its spray-dried active ingredient may include, from which the medical/therapeutic effect is obtained) are molecular types *of a medicament composition* (e.g., used as/in a medicament).

284. Subramaniam teaches that its spray-dried composition's active ingredient "may include ... pharmaceutical actives." EX-1004, [0015]; [1b] above. Accordingly, a POSITA would have thus understood that at least one such pharmaceutical active included in Subramaniam's spray-dried active ingredient (i.e., *one or more principle molecular types*) — being a constituent from which the active ingredient's medical/therapeutic property is obtained, and which is present in a powder that may be used as or in a medicament — is itself a *molecular type of a medicament composition*.

Dependent Claim 16

[16] The spray dried powder of claim 10, wherein the weight percentage of at least one of the one or more principle molecular types in the active ingredient does not vary by more than about 3% during aging of the dried [powder]

during any period of elevated temperature of about 95°F up to about 1000 hours.

285. Subramaniam discloses or renders obvious claim 16 for the reasons in [10c] above. As explained above in [10c], during aging of the dried powder at a temperature of about 95°F for up to about 1000 hours, a constituent principle molecular type of Formulation A's perfume composition (e.g., hexyl salicylate) exhibits 100% recovery—i.e., 0% variation. Thus, a POSITA would have understood that perfuming ingredient's weight percentage (i.e., *the at least one of the one or more principle molecular types in the active ingredient*) varies by 0% during such aging—and thereby *does not vary by more than about 3% during aging of the dried powder during any period of elevated temperature of about 95°F up to about 1000 hours.*

Dependent Claim 17

[17] The spray dried powder of claim 10, wherein the weight percentage of at least one of the one or more principle molecular types in the active ingredient does not vary by more than about 2% during aging of the dried [powder] during any period of elevated temperature of about 95°F up to about 1000 hours.

286. Subramaniam discloses or renders obvious claim 17 for the reasons in

[10c] above. As explained above in [10c], during aging of the dried powder at a temperature of about 95°F for up to about 1000 hours, a constituent principle molecular type of Formulation A's perfume composition (e.g., hexyl salicylate) exhibits 100% recovery—i.e., 0% variation. Thus, a POSITA would have understood that perfuming ingredient's weight percentage (i.e., *the at least one of the one or more principle molecular types in the active ingredient*) varies by 0% during such aging—and thereby *does not vary by more than about 2% during aging of the dried powder during any period of elevated temperature of about 95°F up to about 1000 hours.*

Dependent Claim 18

[18] The spray dried powder of claim 10, wherein the weight percentage of at least one of the one or more principle molecular types in the active ingredient does not vary by more than about 1% during aging of the dried [powder] during any period of elevated temperature of about 95°F up to about 1000 hours.

287. Subramaniam discloses or renders obvious claim 18 for the reasons in [10c] above. As explained above in [10c], during aging of the dried powder at a temperature of about 95°F for up to about 1000 hours, a constituent principle molecular type of Formulation A's perfume composition (e.g., hexyl salicylate)

exhibits 100% recovery—i.e., 0% variation. Thus, a POSITA would have understood that perfuming ingredient’s weight percentage (i.e., *the at least one of the one or more principle molecular types in the active ingredient*) varies by 0% during such aging—and thereby *does not vary by more than about 1% during aging of the dried powder during any period of elevated temperature of about 95°F up to about 1000 hours.*

Dependent Claim 19

[19] The spray dried powder of claim 10, wherein the carrier comprises starch.

288. Subramaniam discloses claim 19.

289. Subramaniam teaches that its *carrier* includes “[s]uitable wall-forming carbohydrate materials,” which includes “natural or modified starch” and that, “[i]n one particular embodiment of the invention, the carbohydrate material is selected from the group consisting of a maltodextrin ... a chemically modified starch, a hydrogenated starch hydrolysate and a succinylated or hydrolyzed starch.” EX-1004, [0024]; *also* EX-1004, [0005] (identifying carriers as “starches, hydrolyzed starches (maltodextrin), chemically modified starches”). The *carrier* of Formulation A in Example 7 comprises 38.20% maltodextrin 18DE by dry weight, which is a hydrolyzed *starch*. EX-1004, [0005], [0065]; [10a] above.

XI. CONCLUSION

290. For all the reasons I have noted in the foregoing paragraphs, claims 1-5 and 7-19 of the '776 Patent are obvious in view of the references discussed above.

291. 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.

APPENDIX A

Dave A. Miller, Ph.D.

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PROFESSIONAL SUMMARY

Translational drug development leader and pharmaceutical executive with 20+ years of experience spanning early-stage biotech formation, product commercialization, CMC strategy, and life science investment. Proven track record of advancing 15 drug products to Phase I clinical trials, overseeing 2 programs through Phase II, one asset to registration stages, and contributing to commercial approval with deep expertise in identifying value inflection points, establishing development milestones, and managing portfolio risk across the full product development lifecycle. Instrumental in securing approximately \$120 million in private equity investment through rigorous technical and commercial due diligence. Experienced in IP strategy, licensing negotiations, and regulatory science, with an oncology focus spanning targeted small molecules and bioavailability-enhanced oncology formulations. Skilled at translating complex scientific and technical concepts for diverse audiences, from R&D teams and regulatory agencies to investors and governing boards, with a demonstrated commitment to operating with accountability, transparency, and public purpose.

CORE COMPETENCIES

- Translational Drug Development & Product Commercialization
- Biotech Portfolio Management & Investment Risk Analysis
- CMC Strategy and Regulatory Expertise
- Intellectual Property Development
- Oncology Drug Development & Clinical Strategy
- Business Development, Licensing & IP Negotiation
- Cross-Functional Team Leadership
- Expert Witness & Litigation Support (Patent / Trade Secret)
- Pharmaceutical Regulatory Science (CMC / FDA)

PROFESSIONAL EXPERIENCE**Chief Scientific Officer****July 2021 to Present***AustinPx, DisperSol Technologies, LLC, Georgetown, TX*

Lead scientific and commercial strategy for AustinPx, a pharmaceutical development and CDMO organization built on the proprietary KinetiSol® platform. Prior to rebranding as AustinPx and the business pivot to a CDMO, I directed the full product development lifecycle for an oncology-focused pipeline, overseeing candidate identification, formulation strategy, CMC development, and clinical translation. Provided expert counsel to the Board on scientific initiatives, investment priorities, and platform positioning. Served as primary scientific interface with investors, partners, and licensing counterparts. Drove business development activities including identification of in-licensing opportunities, technical diligence on external compounds, and evaluation of partnership structures. Led AI/ML-enabled drug discovery initiative to identify insoluble oncology ligands targeting validated pathways.

Specific accomplishments include:

- Developed and implemented a novel drug discovery strategy by leveraging DisperSol's proprietary capabilities and external machine learning tools to identify insoluble ligands targeting validated oncology pathways
- Designed and executed a strategy to leverage external databases and analytical tools for identifying investigational compounds as in-licensing opportunities for the KinetiSol development platform

Expert Witness and Litigation Support**2023 to Present***Various Clients*

Retained as an independent pharmaceutical expert witness in patent litigation and arbitration matters involving pharmaceutical formulation science, CMC development, amorphous solid dispersion technology, lyophilization, dissolution testing, and regulatory science. Provide written expert reports, declarations, and oral testimony (deposition and trial). Retained matters include:

- CASI Pharmaceuticals, Inc. v. Acrotech Biopharma Inc. f/k/a Acrotech Biopharma LLC – American Arbitration Association, Case No. 01-25-0001-6262 (Greenberg Traurig LLP). Expert report submitted March 2026.
- AstraZeneca et al. v. Natco Pharma Limited and Sandoz, Inc. – U.S. District Court, D.N.J. – Lynparza® Hatch-Waxman Litigation. Expert infringement reports submitted December 2025; invalidation rebuttal reports submitted February 2026.
- Veloxis Pharmaceuticals Inc. v. Sun Pharmaceutical Industries – U.S. District Court, D. Del. – Tacrolimus ER tablet patent infringement. Expert report on dissolution testing results submitted December 2025
- AbbVie Inc. v. Aurobindo Pharma U.S.A. – U.S. District Court, D.N.J. – Ubrelvy® Hatch-Waxman Litigation. Expert report on testing results submitted August 2025.
- Mitsubishi Tanabe Pharma Corporation v. Cipla and Apotex – U.S. District Court, D. Del. – Hatch-Waxman Litigation. Expert report on testing results submitted May 2025.
- Bausch Health Ireland Limited and Salix Pharmaceuticals v. MSN Laboratories – U.S. District Court, D.N.J. – Trulance® Hatch-Waxman Litigation. Expert report submitted March 2025; deposition testimony May 2025; trial testimony November 2025.
- Argentum Pharmaceuticals LLC v. Biondelivery Sciences International – USPTO Patent Trial and Appeal Board, Inter Partes Review. Expert declaration submitted February 2025
- Synthon B.V. v. Astellas Pharma Inc. and Medivation Prostate Therapeutics – The Hague, Netherlands – Patent Invalidation. Expert reports submitted; appeared at trial June 2023.

Vice President, Research and Development**September 2011 to July 2021***DisperSol Technologies, LLC, Georgetown, TX*

Led investor due diligence for the Series C financing in April 2014, in which Research Corporation Technologies became the lead investor, with cumulative private equity investment exceeding \$120 million. Served as primary commercial and technical interface with investors, partners, and potential licensees, evaluating business plans, financial projections, and development milestones. Acted as the de facto Chief Evangelist for KinetiSol® technology, delivering targeted seminars to major pharmaceutical companies that resulted in numerous partnered projects and long-term collaborations.

Served as lead scientific strategist, identifying oncology and rare disease opportunities that constituted the entirety of the company's late-stage clinical pipeline. Conducted technical, clinical, and commercial diligence to evaluate new business opportunities, assess value inflection points, and structure milestone-based development plans. Represented the CMC function in FDA meetings and led pharmaceutical development for external client partnerships. Negotiated IP and licensing arrangements and managed a significant portion of DisperSol's patent portfolio in coordination with legal counsel.

Grew R&D organization from one employee in 2011 to 54 full-time employees by 2022, establishing analytical and manufacturing facilities, clinical supply capabilities, and quality systems. Supported preclinical, manufacturing, clinical, and regulatory functions across 15 Phase I programs and 2 Phase II completions. Oversaw competitive IP positioning and contributed to securing 12 granted U.S. patents in collaboration with legal counsel.

Specific accomplishments include:

- Played a pivotal role in securing approximately \$120 million in private equity investments.
- Led the company's growth from a single full-time employee in 2011 to 54 full-time employees by 2022.
- Spearheaded the development of 15 KinetiSol-based drug products that advanced to Phase I clinical trials.
- Successfully developed 2 KinetiSol-based drug products that completed Phase II clinical trials.
- Oversaw the development of 1 KinetiSol-based drug product that progressed to the registration stage.
- Achieved 9 granted U.S. patents for innovations in drug delivery and bioavailability.
- Authored and published 30 peer-reviewed journal articles showcasing scientific advancements.

Senior Principal Scientist*Hoffmann-La Roche, Inc., Nutley, NJ***July 2010 to September 2011**

Directed formulation development teams for investigational small molecules, managing projects from clinical lead selection through post-approval changes. Served as Departmental Project Coordinator for multiple programs at various development stages, fostering cross-functional collaboration, achieving key milestones, and aligning with Technical Development and Global Project Teams. Oversaw activities across pre-formulation, analytical development, formulation development, manufacturing, compliance, and regulatory functions. Led resource planning, developed and maintained project timelines, and provided regular updates to Senior Technical Management. Supervised a team of Associate Principal Scientists and Scientific Technicians, ensuring effective execution of project objectives and fostering professional development within the group.

Specific accomplishments include:

- Directed a global pharmaceutical development team in creating a fixed-dose combination tablet of danoprevir and ritonavir, achieving Phase III readiness and commercial launch under highly accelerated timelines. The product, branded as Ganovo, was approved in China in June 2018. Responsibilities included formulation and process development for melt-extruded danoprevir, spray-dried ritonavir, and the fixed-dose combination tablet, collaborating with legal counsel on IP strategy, contributing to technical development planning, and presenting updates to the Executive Committee.
- Led the development of a post-approval commercial formulation for dalcetrapib, pioneering a novel bottom-up nanoparticle production process using melt extrusion (US Patent Application 20120213827).
- Spearheaded the development of a melt-extruded solid dispersion formulation for danoprevir, supporting its progression through Phase II, Phase III, and commercial launch (US Patent Application 20120114751).

Principal Scientist*Hoffmann-La Roche, Inc., Nutley, NJ***September 2007 to July 2010**

Developed and executed formulation strategies for investigational small molecules across various development stages, from preclinical safety studies to late-phase clinical trials. Designed and implemented experimental pathways to support drug product development, manufacturing, and clinical supply, collaborating closely with analytical, manufacturing, and regulatory teams. Served as Departmental Project Coordinator for multiple programs, driving cross-functional team collaboration, high-level project planning, and the achievement of technical milestones, while regularly updating senior management. Specialized in formulation and process technologies to enhance the oral absorption of BCS II/IV compounds, including solid dispersion systems, hot-melt extrusion, spray drying, and advanced particle engineering techniques. Proficient in conventional pharmaceutical processing operations, such as milling, blending, granulation, tablet compression, and film coating, as well as analytical methods including DSC, XRD, HPLC, SEM, and dissolution testing. Supervised one full-time Associate Principal Scientist and two part-time Scientific Technicians, ensuring effective execution of responsibilities and professional growth.

Specific accomplishments include:

- Awarded Silver Medal for Outstanding Research Poster at Roche Amorphous Technologies Symposium, 2010
- Finalist for Roche Pharma CEO Award for Innovation and Excellence, 2009

Praktikant*Evonik, Darmstadt, Germany***May to August 2005**

Led research and development efforts toward the optimization of functional coating systems based on various grades of Eudragit® polymers. Gained experience in development of functional coating formulations, method development for particle size analysis of colloidal dispersions, film coating process optimization, and physical analysis of film coated substrates.

Graduate Research Assistant*The University of Texas at Austin, Austin, TX***August 2003 to August 2007**

Conducted extensive research in amorphous solid dispersion systems, focusing on process and formulation technologies, solid-state characterization, and performance assessment, including the development of in-vitro/in-vivo correlations. Gained deep expertise in hot-melt extrusion and particle engineering technologies, as well as polymeric film coating for delayed, controlled, and pulsatile release systems. Proficient in solid-state characterization techniques such as differential scanning calorimetry (DSC), x-ray diffraction (XRD), scanning electron microscopy (SEM), energy dispersive x-ray spectroscopy (EDX), physical-mechanical testing of polymer films, particle size analysis by laser diffraction, and surface area determination using the Brunauer-Emmett-Teller (BET) method. Skilled in analytical methods including dissolution testing, high-performance liquid chromatography (HPLC), UV spectroscopy, and planar laser-induced fluorescence imaging. Extensive experience in pharmaceutical unit operations, encompassing hot-melt extrusion, drug particle engineering, film coating, various tablet technologies, wet and dry granulation, wet milling, and extrusion/spheronization. Well-versed in conducting pharmacokinetic studies using rat models.

Specific accomplishments while at the University of Texas include:

- Conceived of and co-developed KinetiSol® technology (US Patents 8,486,423; 9,339,440; 10,022,385; 10,668,085; 11,439,650).
- Co-invented and developed a novel particle delivery technology (US Patent 9,504,658 and 9,730,894); the resulting IP was licensed by AbbVie.
- Authored numerous research articles in leading peer-reviewed journals and two book chapters. Most highly cited publications include:
 - Miller et al. JPharmSci. (2007), 96(2), pp. 361-376 – **191 citations per Google Scholar**
 - Miller et al. PharmRes. (2008), 25(6), pp. 1450-1459 – **184 citations per Google Scholar**
 - Miller et al. DrugDevIndPharm. (2008), 34(8), pp. 890-902 – **204 citations per Google Scholar**
- Presented research at international conferences in the US, Japan, and Brazil.
- Finalist for the 2008 University of Texas Outstanding Dissertation Award

EDUCATION

The University of Texas at Austin

August 2007

Doctor of Philosophy in Pharmaceutics, GPA 4.0/4.0

Dissertation Title: *Improved Oral Absorption of Poorly Water-Soluble Drugs by Advanced Solid Dispersion Systems*

Research Advisors: James W. McGinity, Ph.D. and Robert O. Williams III, Ph.D.

The University of Texas at Austin

December 2002

Bachelor of Science in Chemical Engineering, GPA 3.6/4.0

JOURNAL PUBLICATIONS

Behrend-Keim, Beatriz, Miguel O. Jara, Daniel A. Davis Jr, and Dave A. Miller. *A Modified KinetiSol Process to Produce Dry Powder Blends for Pulmonary Delivery*. **Manuscript in Review**. (2026)

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Mamoru Fukuda, Dave A. Miller, Nicholas A. Peppas, James W. McGinity, "Influence of Sulfobutyl Ether β -Cyclodextrin (Captisol®) on the Dissolution Properties of a Poorly Soluble Drug from Extrudates Prepared by Hot-Melt Extrusion". **2006 AAPS Annual Meeting and Exposition**. San Antonio, TX. October 29 – November 2, 2006.

Dorothea Sauer, Troy P. Purvis, Dave A. Miller, Mirko Gamba, Noel T. Clemens, Robert O. Williams III "Evaluation of the USP Dissolution Test Method A for Enteric-Coated Articles by Planar Laser Induced Fluorescence". **2006 AAPS Annual Meeting and Exposition**. San Antonio, TX. October 29 – November 2, 2006.

Dave A. Miller, Mirko Gamba, Dorothea Sauer, Troy P. Purvis, Noel T. Clemens, Robert O. Williams III. "Evaluation of the USP Dissolution Test Method A for Enteric-Coated Articles by Planar Laser Induced Fluorescence". **66th International Congress of FIP**. Salvador, Brazil. August 25-31, 2006.

Troy P. Purvis, Dorothea Sauer, Dave A. Miller, Mirko Gamba, Noel T. Clemens, Robert O. Williams III. "Evaluation of the USP Dissolution Test Method A for Enteric-Coated Articles by Planar Laser Induced Fluorescence". **2006 Meeting of the Controlled Release Society**. Vienna, Austria. July 22-26, 2006.

Dave A. Miller, Jason T. McConville, James W. McGinity, Robert O. Williams III. "Investigation of Dissolution Properties of Microcrystalline or Stabilized Amorphous Particles of Itraconazole in Melt Extruded Solid Dispersions". **2005 AAPS Annual Meeting and Exposition**. Nashville, TN. November 4-9, 2005.

Dave A. Miller, Jason T. McConville, James W. McGinity, Robert O. Williams. "Investigation of Dissolution Properties of Microcrystalline or Stabilized Amorphous Particles of Itraconazole in Melt Extruded Solid Dispersions". **2005 Hoshi University Joint Symposium**. Tokyo, JP. October 28, 2005.

Dave A. Miller, Jason T. McConville, James W. McGinity, Robert O. Williams. "Miscibility of Hydrophilic Polymers and Surfactants with Polyethylene Oxide in Hot-Melt Extruded Tablets Containing Itraconazole", **2004 AAPS Annual Meeting and Exposition**. Baltimore, MD. November 7-11, 2004.

S. Kucera, J. Tolman, D. Miller, T. Le, W. Zheng, N. Shah, A. Malick, M. Infeld J. McGinity, "The Influence of Proteins on the Physical Stability of Theophylline Matrix Tablets Containing Eudragit® RS/RL 30D", **2004 AAPS Annual Meeting and Exposition**. Baltimore, MD. November 7-11, 2004.

S. Kucera, D. Miller, T. Le, W. Zheng, N. Shah, A. Malick, M. Infeld J. McGinity, “The Influence of Gelatin Type on the Stability of Eudragit® RS/RL 30D Film-Coated Theophylline Pellets”. **2004 AAPS Annual Meeting and Exposition**. Baltimore, MD. November 7-11, 2004.

HONORS & AWARDS

University of Texas College of Pharmacy Distinguished Young Alumnus, *2014*
Silver Medal Award for Outstanding Research Poster, Roche Amorphous Technologies Symposium, *2010*
Finalist for Roche Pharma CEO Award for Innovation and Excellence, *2009*
Rutgers University Mini-MBA: Biopharma Innovation Program, *2009*
The University of Texas Outstanding Dissertation Award Finalist, *2008*
Food, Drug, and Cosmetic Division of the American Society for Quality Control Fellowship, *2006-2007*
Jaime N. Delgado Endowed Graduate Fellowship in Pharmacy, *2006-2007*
AstraZeneca - AFPE Pre-Doctoral Fellowship in Pharmaceutical Science, *2006-2007*
AstraZeneca - AFPE Pre-Doctoral Fellowship in Pharmaceutical Science, *2005-2006*
The University of Texas Chemical Engineering Departmental Scholarship, *Fall 2001, Spring 2002*
University of Texas Honors Day Collegiate Scholar Award, *2001 and 2002*
Six-Time University Honors Recipient, The University of Texas at Austin, *1998 to 2002*

MEMBERSHIPS

Controlled Release Society, *2007 to Present*
Rho Chi Academic Honor Society in Pharmacy, *Fall 2004 to Present*
American Association of Pharmaceutical Scientists, *Fall 2003 to Present*
National Society of Collegiate Scholars, *Fall 2000 to Present*
Academic Fraternities Alpha Lambda Delta and Phi Eta Sigma, *Fall 1999 to Present*

EDITORIAL RESPONSIBILITIES

AAPS PharmSciTech – *Editorial Advisory Board Member and Guest Editor*
Drug Development and Industrial Pharmacy – *Former Editorial Advisory Board Member*
Journal of Pharmacy and Pharmacology - *Reviewer*
European Journal of Pharmaceutics and Biopharmaceutics - *Reviewer*
International Journal of Pharmaceutics – *Reviewer*
Carbohydrate Polymers – *Reviewer*

Graduate Student (Ph.D.) Committee Member

Dr. Stephen Thompson
Dr. Daniel Davis
Dr. Urvi H. Gala
Dr. Scott Jermaine
Dr. Chris Brough
Dr. Justin LaFontaine
Dr. Daniel Ellenberger

Dave A. Miller, Ph.D.

Testimony List Pursuant to Rule 26(a)(2)(B)(v)

- **CASI Pharmaceuticals, Inc. v. Acrotech Biopharma Inc. f/k/a Acrotech Biopharma LLC**
American Arbitration Association / International Centre for Dispute Resolution –
Arbitration Case No. 01-25-0001-6262
 - Expert report submitted March 6, 2026 (retained by Greenberg Traurig LLP on behalf of Acrotech); testimony (deposition/arbitration hearing) pending
- **Eagle Pharmaceuticals, Inc. and Eagle Sub1 LLC v. Slayback Pharma LLC and Azurity Pharmaceuticals, Inc.** U.S. District Court for the District of Delaware – Patent Infringement Litigation, C.A. No. 24-65-JLH (Consolidated)
 - Provided expert report on statistical analysis of drug product stability data contained within the specification of the patents (April 13, 2026); testimony (deposition/trial) pending
- **AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, Kudos Pharmaceuticals Limited, The University of Sheffield, and MSD International Business GMBH v. Natco Pharma Limited, Sandoz Inc., Cipla Limited, Cipla USA, Inc., Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited** U.S. District Court for the District of New Jersey – Lynparza Hatch-Waxman Litigation, Civil Action No. 23-cv-00796 (RK)(TJB) (Consolidated)
 - Expert infringement reports submitted December 2025; Expert response to invalidity reports submitted March 2026; Deposition testimony scheduled for April 30, 2026
- **Veloxis Pharmaceuticals Inc. v. Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries Inc.** U.S. District Court for the District of Delaware - Tacrolimus ER tablet patent infringement lawsuit. C.A. No. 1:24-cv-00726-UNA
 - Provided expert report on dissolution testing results (December 2025); testimony (deposition/trial) pending
- **Bausch Health Ireland Limited and Salix Pharmaceuticals, Inc. v. MSN Laboratories Private, Ltd. and MSN Pharmaceuticals Inc.**
U.S. District Court for the District of New Jersey – Trulance Hatch-Waxman Litigation, Civil Action No. 21-10057 (SRC)(JSA)

- Provided expert report on testing results (March 2025); deposition testimony (May 25, 2025); trial testimony (November 10, 2025)
- **AbbVie Inc. v. Aurobindo Pharma U.S.A.**
U.S. District Court for the District of New Jersey – Ubrely Hatch-Waxman Litigation
 - Provided expert report testing results (August 2025); testimony (deposition/trial) pending
- **Argentum Pharmaceuticals LLC v. Biodelivery Sciences International**
USPTO Patent Trial and Appeal Board – Inter Partes Review, Case IPR2025-XXXXX
 - Expert declaration submitted (February 2025)
- **Mitsubishi Tanabe Pharma Corporation v. Cipla USA Inc., Cipla Limited, Apotex Inc. and Apotex Corp.**
U.S. District Court for the District of Delaware – Hatch-Waxman Litigation, C.A. No. 1:23-cv-00759-JLH-CJB (Consolidated)
 - Provided expert report on testing results (May 2025)
- **Synthon B.V. v. Astellas Pharma Inc. and Medivation Prostate Therapeutics**
The Hague, Netherlands – Patent Invalidation Case
 - Provided expert reports; appeared, but was not called to testify at trial (June 8, 2023)