

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WELLA OPERATIONS US LLC,
Petitioner,

v.

OLAPLEX, INC.,
Patent Owner.

PGR2026-00010
Patent 12,214,225 B2

DECLARATION OF DR. RANDALL WICKETT

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LIST OF DOCUMENTS CITED

Ex. No.	Short Title	Description
1001	'225 Patent	U.S. Patent No. 12,214,225
1002	Gallo	Declaration of Lisa Gallo
1003	225 FH	File History of U.S. Patent No. 12,214,225
1004	NCI	NCI Dictionary of Cancer Terms, National Cancer Institute, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/keratin
2002	Baldwin	Aaron D. Baldwin and Kristi L. Kiick, <i>Tunable degradation of maleimide-thiol adducts in reducing environments</i> , Bioconjug Chem., Vol. 22, Issue 10 (Oct. 19, 2011)
2003	de Berker	D.A.R. de Berker, J. Andre, and R. Baran, <i>Nail biology and nail science</i> , Int'l J. of Cosmetic Science, Vol. 29 (2007)
2004	EMA	European Medicines Agency, <i>Guideline on Excipients in the Dossier for Application for Marketing Authorisation of a Medicinal Product</i> (Jun. 19, 2007)
2005	Feng	Pub. No. US 2008/0075679
2006	Gupchup	Gouri V. Gupchup and Joel L. Zatz, <i>Structural characteristics and permeability properties of the human nail: A review</i> , J. Cosmet. Sci., Vol. 50 (Nov. 1999)
2007	Hill	Paulina Hill, Helen Brantley, and Mark Van Dyke, <i>Some properties of keratin biomaterials: Kerateines</i> , J. Biomaterials, Vol. 31 (2010)
2008	Holzberg	Mark Holzberg, <i>Nails</i> , Chapter 108 from Clinical Methods: The History, Physical, and Laboratory Examinations (3d Ed. 1990), available at https://www.ncbi.nlm.nih.gov/books/NBK211/L
2009	Lynch	Marion H. Lynch <i>et al.</i> , <i>Acidic and Basic Hair/Nail ("Hard") Keratins: Their Colocalization in Upper Cortical and Cuticle Cells of the Human Hair Follicle and Their Relationship to "Soft" Keratins</i> , J. of Cell Biology, Vol. 103, Issue 6, Pt. 2 (Dec. 1986)
2010	Mayo Clinic	Dawn Davis, M.D., Mayo Clinic, <i>What Can Fingernails Reveal About Health?</i> (Nov. 18, 2011), available at https://newsnetwork.mayoclinic.org/discussion/fingernails-are-a-window-to-your-health/

Ex. No.	Short Title	Description
2011	McGrath	J.A. McGrath, R.A.J. Eady, and F.M. Pope, <i>Anatomy and Organization of Human Skin</i> , Chapter 3 of Rook's Textbook of Dermatology (Jan. 1, 2004)
2012	McKittrick	J. McKittrick <i>et al.</i> , <i>The Structure, Functions, and Mechanical Properties of Keratin</i> , JOM, Vol. 64, Issue 4 (2012)
2013	Moll	Roland Moll, Markus Divo, and Lutz Langbein, <i>The human keratins: biology and pathology</i> , Histochem Cell Biol., Vol. 129 (2008)
2014	Zaias	Nardos Zaias, <i>Embryology of the Human Nail</i> , Arch. Dermatol., Vol. 87 (Jan. 1963)
2015	Gniadecka	Monica Giadecka <i>et al.</i> , <i>Structure of Water, Proteins, and Lipids in Intact Human Skin, Hair, and Nail</i> , J Investigative Dermatol., Vol. 110, Issue 4 (Apr. 1998)

I. INTRODUCTION

1. My name is Randall Wickett. I am over the age of twenty-one (21) years, of sound mind, capable of making the statements set forth in this declaration, and competent to testify about the matters set forth below. All the facts and statements contained in this declaration are within my personal knowledge and they are, in all things, true and correct.

2. I have been retained on behalf of Olaplex, Inc. (“Olaplex”), to provide my opinions and views on the materials I have reviewed related to U.S. Patent No. 12,214,225 (the “’225 Patent”). I have been asked to consider what a person of ordinary skill in the art at the time of the alleged invention of the ’225 Patent (which I sometimes refer to as a “POSITA”) would have understood about the issues I address below.

3. My opinions, set forth below, are guided by my appreciation of how a POSITA would have understood the state of the relevant art, the teachings of the references I discuss below, and the claims of the ’225 Patent at the time of the alleged invention (which I may also refer to as the “time of the invention” or the “alleged invention date” or just the “invention date”), which I assume is August 1, 2013, the filing date of the earliest patent application to which the ’225 Patent claims priority.

II. PROFESSIONAL BACKGROUND AND RELEVANT EXPERIENCE

4. My curriculum vitae (“CV”) is attached as Attachment A. My CV highlights my education, experience, and qualifications as an expert in formulating and testing cosmetic and personal care products. Some of the information relevant to this case is summarized below.

5. I received my Bachelor of Arts in Chemistry in 1968 from Western Washington State College. I received a Ph.D. in Biophysics from the Department of Biochemistry and Biophysics at Oregon State University in 1973. I was a postdoctoral fellow at the University of Minnesota, Minneapolis in the Department of Chemistry from 1972-1974, where I studied protein conformational dynamics.

6. I worked in the Cosmetics and Personal Care industry from 1974 to 1991, first at Procter and Gamble in Cincinnati, Ohio from 1974 to 1985 and then at S.C. Johnson Wax in Racine, Wisconsin until 1991. I performed research on products for treating keratin-containing tissues at both of these companies.

7. Since 1991, I have had an extensive consulting practice in which I have performed consulting and training for cosmetic and pharmaceutical companies, including Procter and Gamble, DuPont, Estee Lauder, 3M, Unilever, Clairol, Pfizer, Wyeth Consumer Products, Hill Top Research, Bioscreen, and many others.

8. I am currently Emeritus Professor of Pharmaceutics and Cosmetic Science, University of Cincinnati, College of Pharmacy. I joined the University of

Cincinnati, College of Pharmacy as Associate Professor of Pharmaceutics and Cosmetic Science in 1991 and was promoted to Professor of Pharmaceutics and Cosmetic Science in 1998. In that capacity, I teach graduate classes on cosmetic science including, among other topics, the science of caring for keratin-containing tissues. The Cosmetic Science Program at the University of Cincinnati is one of the few graduate programs in the United States offering a M.S. or Ph.D. degree in pharmaceutical sciences with emphasis in cosmetic science.

9. I have given more than 100 invited lectures and taught classes and workshops in the United States and abroad, including in Thailand, Taiwan, Israel, South Africa, Brazil, Argentina, Guatemala, Chile, Scotland, Estonia, South Korea, The Netherlands, Germany, Russia, Romania, Canada and France. The lectures and classes covered topics on various aspects of cosmetic science and cosmetic product technology.

10. I was elected as a fellow of the Society of Cosmetic Chemists in 1996. I served as the Editor of the Journal of the Society of Cosmetic Chemists from 1991 to 1997 and as the Chairman of the International Society for Bioengineering and the Skin from 2000-2005. I was President of the Society of Cosmetic Chemists in 2011 and am currently chairman of the International Society for Stratum Corneum Research.

11. I have received numerous technical awards from the Society of Cosmetic Chemists including the Maison G. deNavarre Medal Award, the Society's highest honor, awarded to me in 1997 and 2021 for technical contributions to cosmetic science and am the only person to win this award twice. I was appointed an International Corresponding Member of the Chilean Academy of Pharmaceutical Sciences, August 7, 2009. I received the first Lifetime Achievement Award from the International Society for Biophysics and Imaging of the Skin, presented in 2024.

12. I have more than 100 scientific publications. My research has included making and testing all manner of cosmetics and personal care products. Publications that I have authored or co-authored within the preceding ten years are listed on my curriculum vitae. I am also co-editor of the book Practical Modern Hair Science.

13. I am a named inventor on four United States patents and two European patents.

14. Of particular relevance to this matter, I have evaluated the effects of chemical treatment on properties of keratinous tissues including keratin damage. I have also researched ingredients to overcome keratin damage and evaluated viscosity and stability of cosmetic and personal care formulations.

III. COMPENSATION

15. My work on this matter is being billed at \$650/hour. Also, I am being reimbursed for reasonable expenses I incur in relation to my services. My

compensation is not dependent on my testimony or the outcome of this or any other proceeding.

IV. LEGAL CONSIDERATIONS

16. I am not a lawyer, and I offer no legal opinions. For the purposes of this declaration, I have been informed by counsel for Olaplex about certain aspects of the law that are relevant to my analysis, as summarized below.

17. I understand that a POSITA is a hypothetical person. He is not a genius. He thinks along the lines of conventional wisdom. I understand that a POSITA is also a person of ordinary creativity, not an automaton (see Section VII, below, for qualifications of a POSITA) and that a POSITA is presumed to have known the relevant art at the time of the invention. I also understand that in determining who would qualify as a POSITA, it is appropriate to consider criteria such as: (a) the type of problems encountered in the art; (b) prior art solutions to those problems; (c) the rapidity with which innovations are made; (d) the sophistication of the technology; and (e) the education level of active workers in the field.

18. I understand that a claim term is given the meaning that the term would have to a POSITA at the time of the invention, which generally is the ordinary and customary meaning of the term. I further understand that the ordinary and customary meaning of a term may be evidenced by a variety of sources, including the words of the claims themselves, the specification, the prosecution history, and extrinsic

evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

19. I understand that a patent specification must contain a description that enables a POSITA to make and use the full scope of the claimed invention without undue experimentation. I understand that, to be enabling, the specification does not need to describe every embodiment encompassed by a claim and that a claim does not need to specifically exclude inoperative embodiments. Rather, I understand that the specification must adequately guide a POSITA to determine, without undue experimentation, what within the claim is operable and possesses the disclosed utility. Furthermore, I understand that a description can enable a claimed invention even if experimentation is required, as long as that experimentation is not “undue.” In ascertaining whether the description would require “undue experimentation,” I understand that factors considered include: (a) the quantity of experimentation that would be necessary to practice the invention; (b) the amount of direction or guidance provided in the specification; (c) whether working examples are included; (d) the nature of the invention itself; (e) the state of the prior art at the time of filing; (f) the level of skill of practitioners in the field; (g) the predictability or unpredictability of the technology; and (h) the breadth of the patent claims. I am told these are referred to as the *Wands* factors.

20. I also understand that a patent specification must contain an adequate written description of the claimed invention, which is separate from the enablement requirement. I understand that, to comply with this written description requirement, the patent specification must describe the claimed invention in sufficient detail to reasonably convey to a POSITA that the inventor(s) had possession of the claimed subject matter as of the filing date. I understand that a literal description of the claimed invention, including in the claims of the as-filed application, can show possession of the claimed subject matter, although the specification need not describe the claimed invention in the exact terms used in the claims. Furthermore, I understand that in some cases a literal description of the claimed invention may be insufficient to satisfy the written description requirement, such as where the claimed invention broadly covers a generic invention, but the specification does not describe a representative number of embodiments encompassed by the claim. In assessing whether a specification supports such generic claims, I understand that a variety of factors can be considered, including the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter. I further understand that the specification does not need to describe every embodiment encompassed by a generic claim or include examples to support the claim. For example, I understand that there can be adequate written description

support for the claimed invention where the disclosure specifies relevant identifying characteristics like complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

21. I understand that a claim is indefinite if, when viewed in light of the specification and prosecution history, it fails to inform a POSITA about the scope of the invention with reasonable certainty. When assessing whether a claim is indefinite, I understand that courts must take into account that the inherent limitations of language often do not permit absolute certainty. I understand that the degree of precision necessary for a claim to be definite is a function of the nature of the subject matter, and that absolute precision is not required. I further understand that a claim is not indefinite just because it is broad.

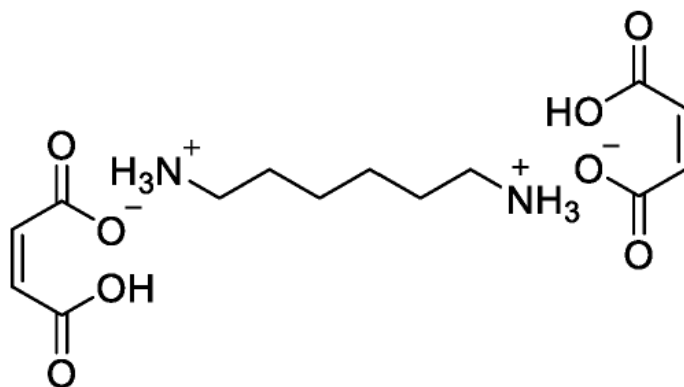
V. BASIS FOR OPINIONS

22. My opinions are based on my education, training, and experience as well as items that I reviewed to prepare my opinions, including the '225 Patent and the publications listed in the table at the beginning of this declaration. All of my opinions are from the perspective of a POSITA—explained below in Section VII—based on their general knowledge, as of no later than August 1, 2013. The documents that I considered and cite include EX2002-EX2015, and my opinion is

that those documents—consistent with them predating August 1, 2013—reflect the knowledge of a POSITA before August 1, 2013. As I address in Section VII, I understand that Ms. Gallo’s definition of a POSITA is different than mine. *See* EX1002, ¶ 59. My opinions would not change if a POSITA had the qualifications set forth by Ms. Gallo (EX1002, ¶ 59). Moreover, my opinions that the Challenged Claims are enabled (Section VIII), supported (Section IX), and clear (Section X) would not change if the invention date is later than August 1, 2013, at least because there was no regression in a POSITA’s knowledge that would detract from a POSITA’s understanding of the ’225 Patent’s keratin treatments.

VI. OVERVIEW OF THE ’225 PATENT

23. The ’225 Patent discloses a “method of treating keratin of a person.” EX1001, Abstract. That “method includes contacting the keratin with a composition comprising a compound” called maleic acid, 1,6-hexanediamine, which has the following “chemical structure”:



EX1001, Abstract, Claim 1. This compound—which I will call the “Active Agent”—is one of the many compounds that the ’225 Patent describes for “repairing ... disulfide bonds” between keratin, which it can do by “react[ing] with thiols” in the keratin “to form covalent bonds.” EX1001, Abstract, 3:30-31, 3:41-44, 4:8-13, 8:20-25, 10:57-61, 11:15-18, 11:33-12:10, 17:51-19:53, col. 16.

VII. PERSON OF ORDINARY SKILL IN THE ART

24. Taking into consideration the factors discussed in paragraph 17, it is my opinion that, as of August 1, 2013, a POSITA would have had a bachelor’s degree in chemistry, biology, chemical engineering, pharmacy, or a related field (including interdisciplinary fields involving chemistry and/or biology like biochemistry or biophysics) and at least four years of experience in cosmetic science. A POSITA having more education could have had less experience. For example, a hypothetical individual having an advanced doctorate degree in any of the above fields would have qualified as a POSITA with at least two years of experience in cosmetic science. With the ’225 Patent disclosing “[a] method of treating keratin of a person” (EX1001, Abstract), the pertinent art concerns keratin treatments. And as reflected in the pertinent art, a POSITA would have been familiar with keratin and the chemistry thereof across various keratin-containing substrates, including in hair, nails, and other parts of the skin. *See, e.g.*, EX2007, 585 (“Keratins are a family of structural proteins that can be isolated from a variety of tissues.”); EX2012, 449-451

(providing overview of different forms of keratin and “the molecular structure” thereof).

25. My definition of a POSITA differs in some respects from that offered by Ms. Gallo (EX1002, ¶ 59). First, Ms. Gallo’s opinion that a POSITA is limited to a “degree in chemistry” (EX1002, ¶ 59) is unduly narrow. Given the multidisciplinary nature of cosmetic science, fields outside of chemistry—as I list above—are also relevant. Simply put, individuals with chemistry degrees were not the only ones working in the field. Second, while I agree with Ms. Gallo that a POSITA would have had experience “in hair and skin” (EX1002, ¶ 59), I disagree with her later implication that a POSITA would have been unfamiliar with “nail cosmetic chemistry” (EX1002, ¶¶ 128-129). It was known that “nails are part of [the] skin” and that “[h]air keratins are . . . found abundantly in hair and fingernails,” so a hypothetical individual familiar with keratins—including in hair and skin—would have been familiar with nails and the keratin thereof. EX2010, 1; EX2007, 585; EX2008, 536; EX2009, 2604. In accordance with this familiarity, workers in the field had—as a POSITA would have had—working experience with all these keratin-containing substrates. *See, e.g.*, EX2005, ¶¶ [0003], [0019], [0062] (“care and/or makeup and/or treatment composition for keratin materials,” including “skin, hair, nails, eyelashes, eyelids, eyebrows, [and] lips”).

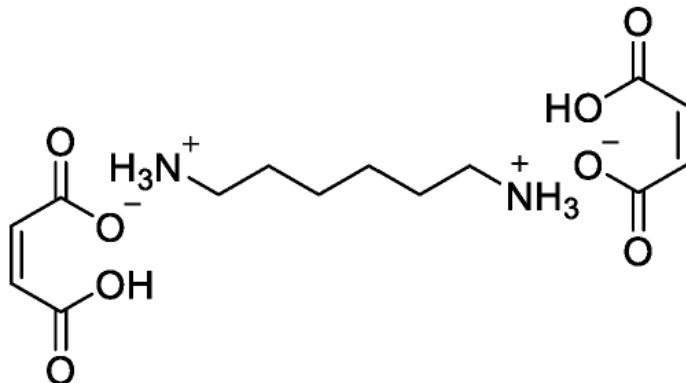
26. By August 1, 2013, my level of skill in the art was at least that of a POSITA, both under my definition set forth above and the definition offered by Ms. Gallo. Furthermore, based on my education and experience, which included training individuals who qualify as POSITAs and some who have at least the academic qualifications of a POSITA, I am well acquainted with the level of ordinary skill described above. Thus, I am capable of rendering an informed opinion on the level of ordinary skill in the art as of August 1, 2013.

VIII. A POSITA WOULD HAVE BEEN ABLE TO MAKE AND USE THE CLAIMED METHODS WITHOUT UNDUE EXPERIMENTATION

27. I understand that Wella maintains that “the Challenged Claims are not enabled by the disclosure,” relying on Ms. Gallo’s “opinion that the ’225 patent only includes sufficient disclosure for a POSA to make a composition comprising the claimed binding agent of claim 1 and use it to treat keratin of a person’s hair (and potentially skin)” but “does not provide any disclosure for a POSA to prepare a composition comprising the binding agent of claim 1, that is suitable and effective for use in other substrates, such as nails, and does not provide any disclosure for using that composition to treat keratin found in nails.” Pet., 14; EX1002, ¶¶ 70, 119. Under the standard set forth above in paragraph 19, I disagree because a POSITA would have been able to implement the claimed methods without undue experimentation.

28. Independent claim 1 of the ’225 Patent recites:

A method of treating keratin of a person, the method comprising contacting the keratin with a composition comprising a compound having a chemical structure of:



The claimed compound is maleic acid, 1,6-hexanediamine, the Active Agent I described above in Section VI. It is one of the many “active agents”—which the ’225 Patent sometimes calls a “binding agent[]”—described in the ’225 Patent to “rebuild latent disulfide bonds” in keratin. EX1001, Abstract, 2:17-31, 3:41-46, 7:53-62, 8:52-9:3, 15:1-19:55 (Active Agent in column 16).

29. I agree with Ms. Gallo that the ’225 Patent “includes sufficient disclosure for a POSA to make a composition comprising the claimed [Active Agent] of claim 1” (EX1002, ¶ 119), whose chemical structure is clearly depicted and would have been obtainable with a known acid-base reaction between a diamine (hexanediamine) and a dicarboxylic acid (maleic acid). *See* EX1001, Abstract, 8:53-9:59, 11:15-12:10, 16:1, Claim 1. I further agree with Ms. Gallo that the ’225 Patent “includes sufficient disclosure for a POSA to . . . use [the claimed composition] to

treat the keratin of a person's hair.” EX1002, ¶ 119. However, I disagree with Wella's and Ms. Gallo's contention that there is inadequate disclosure “to prepare a composition comprising the [Active Agent] of claim 1, that is *suitable and effective for use in other substrates, such as nails*.” EX1002, ¶ 119, Pet. 14-30.

A. The '225 Patent's Disclosure Shows That the Claimed Active Agent Is Operable to Treat Different Forms of Keratin

30. Contrary to Wella's contention that “the '225 patent is directed to methods of treating hair” (Pet., 15), the '225 Patent describes a “method of treating keratin of a person,” which is not limited to hair treatments and includes, for example, “treating . . . skin,” of which nails are a part. EX1001, Abstract, 1:34-36; EX2010, 1 (“Your nails are part of your skin.”). And consistent with this broader applicability and as detailed below, the '225 Patent's disclosure shows that the claimed Active Agent is operative to treat these different forms of keratin, including keratin in nails. This undermines Wella's and Ms. Gallo's position that a POSITA would have been unable to use the claimed composition to treat certain “keratin in the human body” like nail keratin. Pet., 15-16; EX1002, ¶ 119.

1. The '225 Patent Describes a Common Mechanism of Action

31. To begin, the '225 Patent describes that the claimed Active Agent can treat keratin in a way that is applicable to all forms of keratin, evidencing a POSITA's ability to treat more than just hair with the claimed Active Agent.

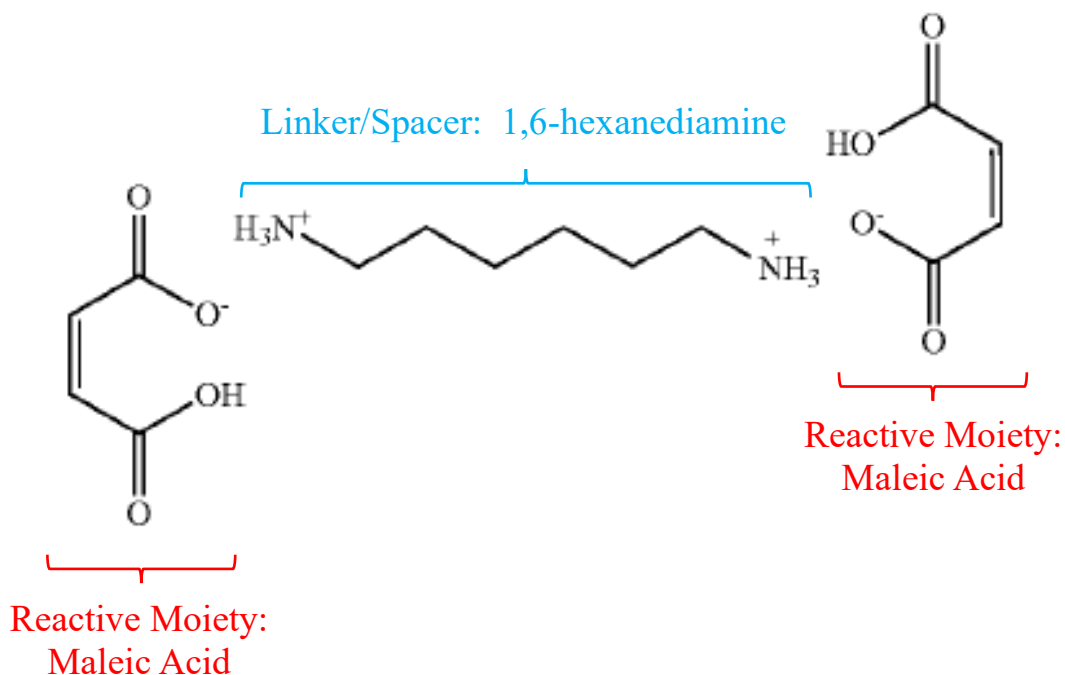
EX1001, 1:34-43, 2:17-31, 3:7-8, 3:15-17, 3:30-52, 7:56-58, 8:20-22, 10:57-59.

Wella and Ms. Gallo fail to adequately address this.

32. In particular, and as the '225 Patent describes using “hair” as an illustration, keratins are “protein chains” that “are bound to each other” with “disulfide bonds.” EX1001, 1:34-43. Those “disulfide bonds” can be broken, which can leave “latent free thiols” (-SH) in the keratin that require “repair.” EX1001, 1:51-2:25, 3:7-8. Per the '225 Patent, and as a POSITA knew, “disulfide bonds” and the “free thiols” resulting from their breakage were not unique to hair keratin—they were present in all human keratins. EX1001, 1:34-36, 2:28-31, 3:15-17 (also in “skin”); EX2012, 449 (“Keratin has a large amount of cysteine residues, which have a thiol group (-SH), producing a strong, covalent disulfide bond.”); EX2007, 586 (keratins “are characterized by a high sulfur content and extensive disulfide bonding”).

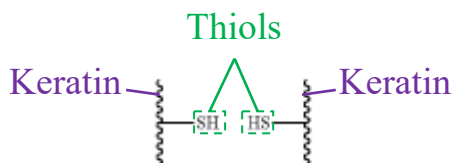
33. Importantly, the '225 Patent teaches that its active agents, including the claimed Active Agent, can treat keratin by “react[ing] with” this common feature of keratins—“thiols”—to “repair[] disulfide bonds.” EX1001, 1:34-43, 2:17-31, 3:7-8, 3:15-17, 3:30-52, 7:56-58, 8:20-22, 10:57-59. To do so, the '225 Patent’s active agents “contain[] a linker or spacer and two or more reactive functional groups” that are bonded “to the linker or spacer,” where the “reactive moieties [can] react with thiols to form covalent bonds.” EX1001, 4:8-13, 8:20-25, 10:57-59. For the Active

Agent recited in claim 1, as annotated below the “linker or spacer” [blue] is 1,6 hexanediamine—a linear diamine linker with six carbon atoms—and each of the “reactive moieties” [red] is “maleic acid,” one of the ’225 Patent’s Michael acceptors that are “capable of reacting with a thiol group”:

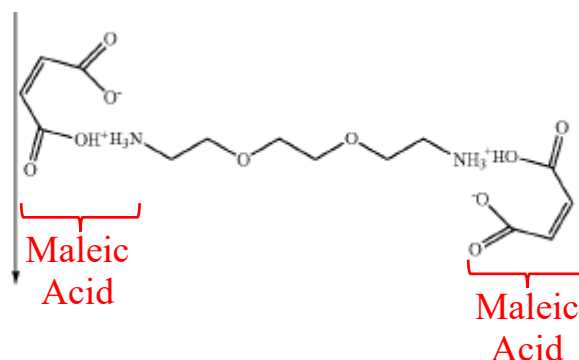


EX1001, 8:20-22, 10:57-59, 11:15-18, 11:33-12:10, col. 16. The ’225 Patent illustrates how the maleic acid reactive moieties of the claimed Active Agent “react with thiols [green] to form covalent bonds [orange]” and thereby join two keratin proteins [purple], as shown below:

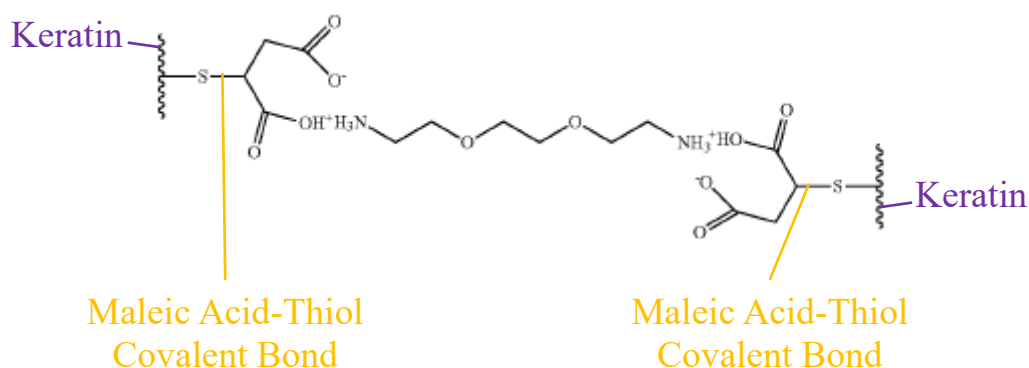
Step 1: Keratin With Free Thiols



Step 2: Contact With Maleic Acid Compound



Step 3: Compound Joins Keratin Via Maleic Acid-Thiol Bonds



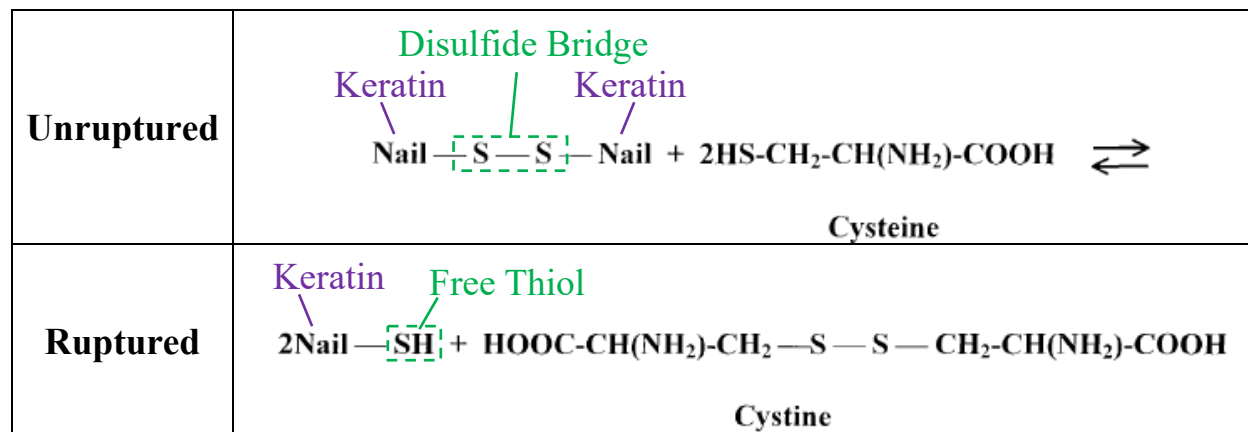
EX1001, 8:20-22, 10:57-59, 17:51-19:53.

34. This reaction occurs because each maleic acid moiety of the Active Agent contains an α,β -unsaturated carbonyl group that functions as an electrophilic Michael acceptor (EX1001, 5:1-3, 11:34-44), which undergoes “nucleophilic

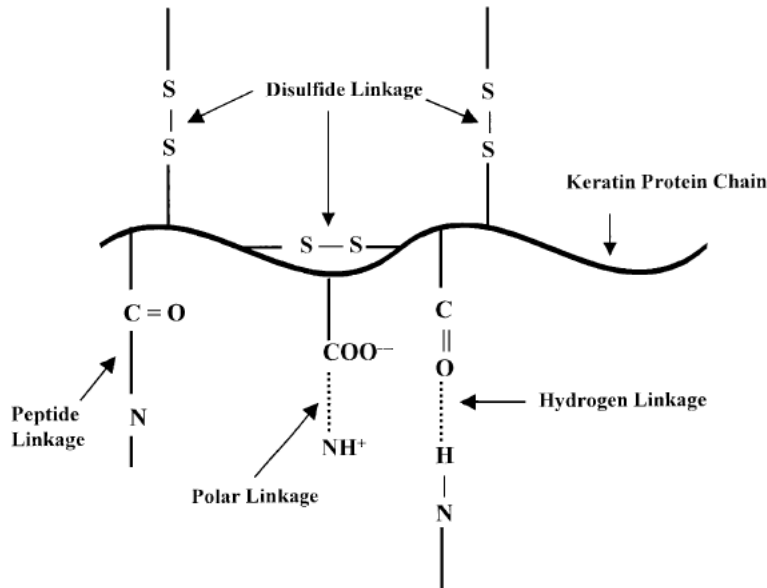
addition reactions” (EX1001, 4:66-5:1) with the thiol group in keratin such that “the sulfur atom of the thiol group becomes covalently bonded to” the Michael acceptor (EX1001, 13:13-15). This reaction, commonly known as a thiol-Michael addition, results in the formation of stable carbon-sulfur covalent bonds between the binding agent and the keratin structure. And because the two reactive maleic acid moieties of the claimed Active Agent are connected by the hexanediamine linker, the Active Agent can bind to two separate free thiol groups on two keratin protein chains to cross-link them, thereby “repairing disulfide bonds.” EX1001, 1:34-36, 3:30-44, 8:20-25, 12:7-10, col. 16, 17:51-19:55.

35. Wella and Ms. Gallo do not dispute that the claimed Active Agent binds to free thiols in keratin in this way. Pet., 15-16; EX1002, ¶¶ 77, 111. While they note that the ’225 Patent “illustrat[es] the actions of binding agents” in hair examples like as shown above (Pet., 15-16; EX1002, ¶¶ 77, 111; EX1001, 17:51-52), they neglect to address a POSITA’s knowledge that the same actions apply to keratins generally, as all “[k]eratin has a large amount of cysteine residues, which have a thiol group (-SH)” with which the Active Agent can bind in the way the ’225 Patent describes, as set forth above. EX2012, 449; EX2007, 585-586; EX1001, 1:34-36, 2:28-31, 3:15-17 (applying beyond hair). For example, as Gupchup illustrates in its FIG. 6 (annotated below), keratin in nails—the only substrate that Ms. Gallo contends a POSITA would not have been able to treat (EX1002, ¶¶ 107, 119)—has

disulfide bonds that are rupturable to yield free thiols just as the '225 Patent illustrates for hair:



EX2006, 378-379. Thus, as a POSITA knew and as illustrated below in FIG. 5 of Gupchup, these disulfide bonds (when “cleaved” to leave a free thiol “-SH group”) were “potential interaction sites for nail” treatments, which aligns with the '225 Patent’s illustration of this mechanism of action for its Active Agent. EX2006, 378-379; EX1001, 17:50-18:52; *see also* EX2014, 37, 49, 52 (“Sulfhydryl stains”—which are stains that bond with free thiols that are also called “sulfhydryl” groups—achieve “positive” reactions in nail),



The applicability of this mechanism of action to keratin generally would have been confirmed by the '225 Patent's broader disclosure that its active agents' "reactive moieties [] react with thiols to form covalent bonds" (EX1001, 10:57-59), where "reacti[ons] with a thiol group in the hair or on the skin" are exemplary (EX1001, 10:59-61). With all keratins "belong[ing] to the family of [intermediate filament] proteins and therefore shar[ing] common protein-structural characteristics," including "a large amount of cysteine residues, which have a thiol group (-SH)" with which the claimed Active Agent could interact, a POSITA would have been able to use the claimed Active Agent to treat keratins generally. EX2013, 707; EX2012, 449.

36. As the above reflects, the '225 Patent's specification would have demonstrated, for a POSITA, that the claimed Active Agent can treat keratin generally through a well-defined chemical mechanism: the maleic acid moieties

reacting with free thiol groups via thiol-Michael addition to form stable covalent bonds. This reflects that a POSITA would have been able to make and use the claimed keratin treatment.

2. Wella's and Ms. Gallo's Acknowledgments Regarding a POSITA's Ability to Treat Hair and Skin Confirms Operability for Nails

37. The only treatment Ms. Gallo identifies as encompassed by the claims but not enabled is “using [the] composition to treat keratin found in nails.” EX1002, ¶¶ 107, 119. While I disagree at least because the claimed Active Agent's mechanism of action would have applied to nail keratin as explained above in Section VIII.A.1, Ms. Gallo's and Wella's acknowledgement that the '225 Patent has sufficient disclosure to allow a POSITA to use the claimed composition “to treat the keratin of a person's hair”—and their tacit acknowledgement of its operability for “skin”—further supports my opinion that a POSITA would have been able to use the claimed Active Agent to treat nail keratin. EX1002, ¶¶ 110, 119; Pet., 15-16 (“Patent Owner at best only enables . . . treating hair keratin and treating skin keratin”). This is because nails were part of the skin and had a similar keratin content as hair, with nail keratin including the same keratin that is contained in hair.

38. To begin, a POSITA knew that “nails are part of [the] skin.” EX2010, 1. In particular, nails are “an infolding of skin that occurs at the terminal end of each digit, creating four specialized components: proximal nail fold, matrix, nail bed, and

hyponychium.” EX2008, 536. Each of these four components and associated structures, illustrated by FIG. 1 of EX2014, reproduced below, originates from the stratified epithelium of skin, where the “nail plate is composed of compacted keratinized epithelial cells.” EX2003, 251; EX2014, FIG. 1; *see also* EX2008, 536; EX2014, 38-39; EX2011, 3.1-3.2, 3.7-3.8. This undermines Wella’s and Ms. Gallo’s contention that the ’225 Patent “potentially [enables] skin” treatments but not nail treatment. Pet., 15-16; EX1002, ¶ 119.

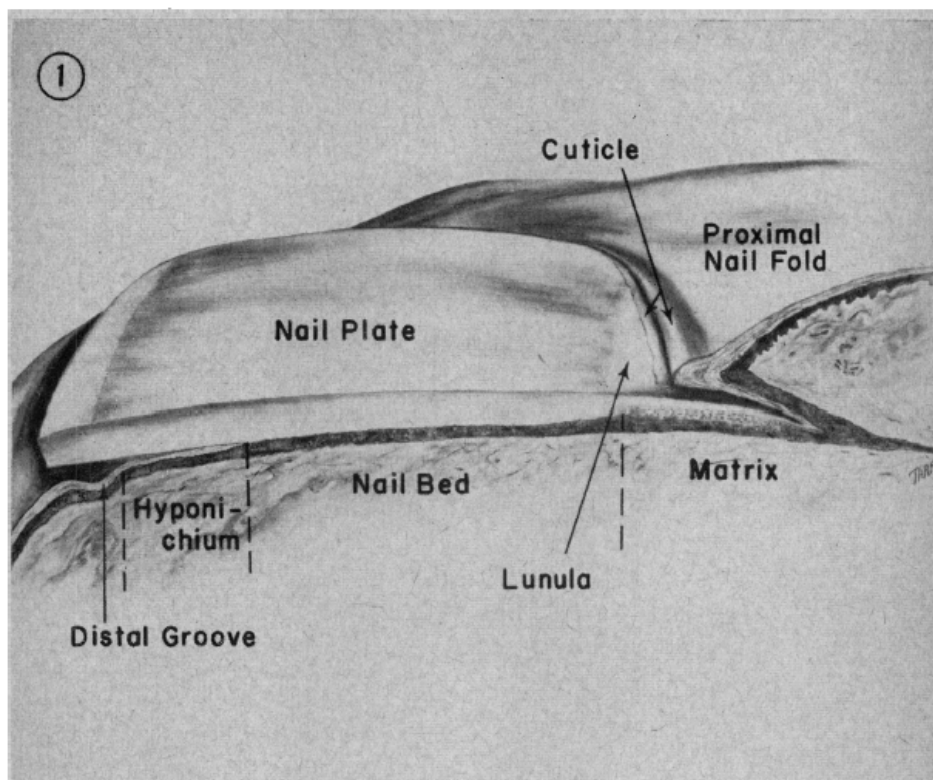


Fig. 1.—Diagrammatic drawing of an adult finger tip, showing nail structures through a longitudinal, midline plane.

39. Further undermining Wella’s and Ms. Gallo’s position, not only are nails part of the skin, but the keratins in hair and nails are remarkably similar. First, “[h]air keratins are . . . found abundantly in hair *and fingernails*” (EX2007, 585),

and the “nail plate contains . . . an *apparently complete set of hair keratins*.” EX2009, 2604. A POSITA’s ability to use the claimed Active Agent to treat keratin in hair—as Ms. Gallo admits (EX1002, ¶ 119)—thus reflects a POSITA’s ability to use the Active Agent to treat that same “set of hair keratins” in the “nail plate.” EX2009, 2604; EX2007, 585.

40. The nail plate’s inclusion of “~10-20% of soft keratins” in addition to the “complete set of hair keratins” does not change this. EX2009, 2604. As explained above in Section VIII.A.1, all keratins—including “soft” keratins—have “a large amount of cysteine residues which have a thiol group (-SH)” that the claimed Active Agent can interact with to treat the keratin, with “soft” keratins merely “ha[ving] less sulfur and therefore fewer cross links” than the “hard” keratins included in “nails” and “hair.” EX2012, 449; EX2007, 485. Thus, as a POSITA would have recognized, the claimed Active Agent would have been operable to treat the “soft” keratins in nails, in addition to the “hard” keratins thereof, even if to a different extent. Indeed, consistent with the “appendages most closely related to nail includ[ing] hair,” the keratin content of nails—comprising “an apparently complete set of [hard] hair keratins” with “~10-20% of soft keratins”—was closer to that of hair than to that of other parts of the skin, where the “keratin is almost exclusively” soft. EX2012, 449; EX2003, 256, 261; EX2009, 2604; *see also* EX2015, 395 (hair and nail keratin disulfide bonds—the relevant part of the molecule for the Active

Agent’s thiol bonding—share the same conformation, that is, the same geometry). A POSITA that would have been able to use the claimed Active Agent to treat skin and hair keratin—which Wella and Ms. Gallo do not dispute (Pet., 15; EX1002, ¶ 119)—thus would have readily been able to do the same for nails.

B. Selecting Excipients & Concentrations Thereof Would Have Been Routine

41. While the claimed composition includes the Active Agent that is operable to treat keratin, Wella maintains that the ’225 Patent “fails to enable *all treatments* for keratin using the proposed structure” because the claims are open with respect to the *excipients*—the “constituents of a pharmaceutical form apart from the active substance” (EX2004, 3)—like “short-chain alcohol and water” that can accompany the Active Agent. Pet., 17; *see* EX1001, 19:56-23:67 (describing the “[c]osmetically acceptable excipients” that the formulations can contain). I disagree. With possession of the Active Agent, a POSITA would have been able to select which, if any, excipients to include in the composition alongside the Active Agent as a matter of routine design, including to address any substrate-specific needs.

42. Wella first argues that “the specification clearly lays out that water must be an ingredient; there simply is no enablement for a treatment using a composition under claim 1 that does not contain water.” Pet., 17. That is incorrect. The portion of the ’225 Patent that Wella cites teaches that “[w]ater is the *preferred* diluent”—not a required diluent. EX1001, 23:29-35. And beyond that, the ’225 Patent

describes that “diluent[s]” like “water” are optional “excipients.” EX1001, 7:61-64 (“The binding agents *can be*”—not must be—“combined with one or more pharmaceutically acceptable carriers and/or excipients”), 19:56-58 (“The formulations *typically*”—not always—“contain one or more cosmetically acceptable excipients” like “water”), 23:29-35. Wella’s position that water is necessary—and thus must be claimed—is not one a POSITA would have shared.

43. Wella next argues that, even for the claims that require water as an excipient, the ’225 Patent’s “disclosure is simply insufficient to warrant patent protection for *all* of the different concentrations of water and short-chain alcohol.” Pet., 17-18. This is because, according to Wella, “not all keratin substrates are treated equally” such that different “water” and “short-chain alcohol” contents “may be ideal for” different substrates and “effective treatments must be tailored to the needs of the specific substrate.” Pet., 18-19. I again disagree that the claims’ openness to a range of water and alcohol concentrations would have precluded a POSITA from carrying out the claimed treatment.

44. At the outset, the purported effects of different water and alcohol concentrations that Wella and Ms. Gallo identify—“improved conditioning and moisturizing for hair and/or skin,” “‘dryness, brittleness, and frizz’ on hair,” and “‘irritation, including burning, redness, itching’ in skin”—are neither required nor precluded by the claim, which recites “treating keratin” (such as by “reacting with a

thiol” of keratin to “rebuild latent disulfide bonds”). Pet., 18-19; *see* EX. 1001, Claim 1, 3:30-33, 7:56-58, 8:20-22, 10:57-59. Thus, a POSITA’s ability to select appropriate water and alcohol concentrations to achieve or avoid these effects does not speak to a POSITA’s ability to perform the claimed keratin treatment, which comprises “contacting the keratin with a composition comprising” the Active Agent.

45. Nevertheless, as guided by the specification’s teaching that formulations “typically contain greater than one percent (wt) water, preferably greater than five percent (wt) water, more preferably greater than 50% (wt) water, and most preferably greater than 80% (wt) water” (EX1001, 23:30-35), a POSITA would have been able to readily determine appropriate water and alcohol concentrations for the claimed composition without undue experimentation—as detailed further in Section VIII.C—including to meet any purported substrate-specific needs. This aligns with Ms. Gallo’s opinions. For example, Ms. Gallo opines that “*a POSA would know* that for hair and skin, the concentration of short-chain alcohols . . . must be low” while “for nails” a “*POSA in 2013 would most likely be aware* that . . . nail treatment formulations would contain much higher levels of volatile organic compounds.” EX1002, ¶¶ 83-86, 117. While I do not fully agree with Ms. Gallo’s opinions regarding the effects of alcohol and water on skin

and hair,¹ I agree with her sentiment that a POSITA would have been well-equipped to determine appropriate excipient concentrations for the composition for various keratin-containing substrates.

C. The *Wands* Factors Support Enablement

46. I have been asked to consider the *Wands* factors set forth in paragraph 19, which I understand are weighed to determine whether undue experimentation would have been required for a POSITA to practice the claimed methods. Wella and Ms. Gallo address each of the *Wands* factors in pages 19-31 of the Petition and paragraphs 121-157 of Ms. Gallo's declaration, respectively, and I respond to their analyses of each factor below.

1. Breadth of the Claims

47. While Wella and Ms. Gallo argue that the Challenged Claims are "precariously broad" or "overly broad" (Pet., 20-24; EX1002, ¶¶121-125), I disagree. The breadth of claim 1 (and thus of its dependent claims) is quite

¹ For example, her opinion that "the concentration of short-chain alcohols ... must be low" for skin because "formulations containing high concentrations of short-chain alcohols can cause irritation" (EX1002, ¶¶ 83, 86) is at odds with the routine use of high-alcohol-content hand sanitizers that are less damaging to the skin compared to, for example, regular hand washing with soap.

circumscribed: it recites treating a specific “family of [] proteins” that “share common protein-structural characteristics” (“keratin of a person”) in a specific way (“contacting the keratin with a composition”) and with a specific active ingredient (maleic acid, 1,6-hexanediamine) that—as set forth in Section VIII.A.1—can treat the claimed family of proteins through a common mechanism of action. EX1001, Claim 1; EX2013, 707. The variations in claim scope that Wella and Ms. Gallo identify do not render the claims “precariously” or “overly broad” as they contend.

48. Wella and Ms. Gallo first maintain that the claimed “keratin of a person” encompassing more than “keratin of the skin and hair” renders the claims “overly broad” compared to the specification that purportedly “is solely directed to formulations and methods for treating keratin found in hair.” Pet., 20-22; EX1002, ¶¶ 121-122, 125. This is a mischaracterization of the specification, which describes “treating keratin of a person” without limitation to hair or skin (EX1001, Abstract), including by “repair[ing] latent free thiols,” which the ’225 Patent teaches its Active Agent can do without limitation to hair and skin, with hair and skin being exemplary substrates (EX1001, 3:7-8, 3:15-17, 8:20-22, 10:57-59). However, beyond that, the claimed treatment being for “keratin of a person” is commensurate with the Active Agent being used for the treatment. This is because, as detailed in Section VIII.A.1, keratins “share common protein-structural characteristics,” including “a large amount of cysteine residues, which have a thiol group (-SH)” that the claimed Active

Agent can interact with to treat keratin through a well-defined chemical mechanism: a thiol-Michael addition reaction through which the Active Agent forms stable carbon-sulfur covalent bonds with the thiol. EX1001, 3:41-44, 8:20-25, 10:57-61, 17:50-19:25; EX2013, 707; EX2012, 449. Wella contends that different unclaimed “result[s]” would have been “desired” for different keratin-containing substrates (like “moisturizing” for “hair” and “skin”) and different excipient choices (like “water concentration” or “organic solvents”) would have been appropriate to achieve those different results. Pet., 20-23. This contention (even if accepted) does not reflect inordinate breadth. The core of the claimed treatment is the recited Active Agent, not auxiliary excipients like “water and alcohol” (Pet., 20-23), and the Active Agent’s ability to treat the variety of keratins (Section VIII.A) renders the claims appropriately tailored to treating “keratin of a person.”

49. Wella next maintains that the Challenged Claims are “precariously broad” because, while they specify *one* Active Agent, they purportedly “could comprise *any material or combination of materials without limitation*,” such as “formulations with no water at all, every variety of water concentration ... and any concentration of short-chain alcohol . . . as well as a whole gamut of combinations of components.” Pet., 23-24. As this reflects, Wella’s position is based on the Challenged Claims’ openness to the *excipients* like “water” and “alcohol” that can accompany the claimed Active Agent. Pet., 23-24; EX1001, 19:56-23:67

(describing the “[c]osmetically acceptable excipients”). Again, these are auxiliary components to the claimed Active Agent, as reflected by the ’225 Patent’s disclosure that the Active Agent “*can be*”—not must be—“combined with one or more pharmaceutically acceptable carriers and/or excipients” as well as a POSITA’s understanding that “[e]xcipients are the constituents . . . *apart from the active substance.*” EX1001, 7:61-64; EX2004, 3. Openness with respect to excipients like “water” and “alcohol” that merely “dilute[] the binding agent” (Pet., 23-24; EX1001, 23:29-38) does not reflect inordinate breadth when the core of the claimed keratin treatment—the Active Agent—is specifically defined.

50. In view of the above, this factor weighs in favor of enablement.

2. Relative Skill of Those in the Art and State of the Prior Art

51. Wella, relying on Ms. Gallo’s definition of a POSITA, contends that a POSITA would have had a “relatively lower level of skill” that would require “more guesswork in arriving at a method of treating *all* keratin,” and specifically with “arriv[ing] at a formulation or method for treating nails.” Pet., 27-28; EX1002, ¶¶ 59, 126-127. I disagree with that characterization of the level of ordinary skill, especially in the view of the claim scope that Wella identifies as purportedly broad.

52. As set forth in Section VII, Ms. Gallo and I agree that a POSITA would have had at least “a bachelor’s degree” with “at least four years of experience in cosmetic science” or an “advanced degree” with “at least two years of experience in

the same field,” although my opinion is that those degrees can be in disciplines other than chemistry. EX1002, ¶¶ 59, 127. Under either definition, there is no dispute that this level of skill was adequate to make and use the claimed Active Agent, including at least to treat hair keratin. EX1002, ¶ 119. And that level of skill was plainly adequate to apply the Active Agent to the various keratins, given—as discussed in Section VIII.A—a POSITA knew that keratins “share common protein-structural characteristics” and include “a large amount of cysteine residues, which have a thiol group (-SH)” with which the claimed Active Agent can interact to treat them in the same way. EX1001, 3:41-44, 8:20-25, 10:57-61, 17:50-19:25; EX2013, 707; EX2012, 449. This is especially true for the nail keratin Wella maintains would have “require[d] additional time and experimentation” (Pet., 27), since—as explained in Section VIII.A.2—a POSITA knew that the “appendages most closely related to nail include hair” and the “nail plate contains . . . an *apparently complete set of hair keratins*,” reflecting that little to no guesswork would have been required. EX2003, 256; EX2009, 2604.

53. Relying on Ms. Gallo’s opinion that a “POSA in hair cosmetic chemistry[] would not be a POSA of nail cosmetic chemistry” because “companies have distinct groups or divisions” for those substrates (EX1002, ¶¶ 128-130), Wella maintains that there “is commonly little crossover” such that “additional time and experimentation” would have been required to “treat[] nails.” Pet., 27-28. As I

explained in paragraph 25, I disagree that a POSITA would not have had experience treating nails. It was known to make formulations for these different keratin-containing substrates, which aligns with my experience that workers in the industry had experience with both. *See, e.g.*, EX2005, ¶¶ [0003], [0019], [0062] (“care and/or makeup and/or treatment composition for keratin materials,” including “skin, hair, nails, eyelashes, eyelids, eyebrows, [and] lips”). And Wella and Ms. Gallo appear to miss that we are talking about a hypothetical individual presumptively aware of all of the relevant art (as I understand, from paragraph 17), which for a “method of treating keratin” (EX1001, Abstract, Claim 1) would have included familiarity with “the variety of tissues” that contain “[k]eratins,” especially nails whose keratins include an “apparently complete set of hair keratins.” EX2007, 585; EX2009, 2604.

54. Further, the required “experimentation” that Wella references, through citation to Ms. Gallo’s declaration, concerns the selection of “excipients” like “water” to accompany the Active Agent for the nail treatment. Pet., 27-28; EX1002, ¶¶ 142-144. A POSITA—with a bachelor’s or advanced degree and cosmetic science experience—that undisputably would have been able to make the claimed Active Agent (EX1002, ¶ 119) plainly would have been able to select excipients like those the ’225 Patent describes (EX1001, 19:56-23:67) to accompany the Active Agent, as detailed further in Sections VIII.C.3-5.

55. Finally, Wella maintains if a POSITA had “a greater level of skill” than what Ms. Gallo offered, such a POSITA would have had “a greater understanding of the differences between hair and nails” and thus “would not have found the teachings of the ’225 patent to have any pertinence to nails.” Pet., 27-28. This contention is irreconcilable with the existing knowledge concerning hair and nail keratin, especially because the “nail plate contains . . . an apparently complete set of hair keratins.” EX2009, 2604.

56. In view of the above, these factors weigh in favor of enablement.

3. Amount of Direction or Guidance Presented and Presence of Working Examples

57. Wella contends that “there simply is no direction anywhere within the ’225 patent guiding . . . a method of treating *all keratin*, let alone keratin in nails” because the “specification presents eight examples of methods of treating *hair*” but none for “treating keratin in *any other form*.” Pet., 28-30; EX1002, ¶¶131, 135-136. I disagree.

58. First, as detailed Section VIII.A.1, the ’225 Patent provides extensive direction regarding the applicability of the claimed treatment to the various keratins: it describes (1) the chemical structure of the Active Agent used (EX1001, Abstract, 7:61-62, 8:20-24, 11:15-18, 12:1-10, col. 16), and (2) how the Active Agent’s “two reactive moieties”—the maleic acid moieties—can “react with thiols to form covalent bonds” to repair “disulfide bridges” and thereby treat keratin, a mechanism

of action that applies to more than just hair keratin because all keratin “has a large amount of cysteine residues, which have a thiol group (-SH)” (EX1001, 2:17-31, 10:57-61, 17:50-19:25; EX2012, 449). The ’225 Patent’s “eight examples of methods of treating *hair*” successfully with a “bismaleate binding agent” (meaning it had the same maleic acid reactive moieties as the claimed Active Agent) (Pet., 28; EX1001, 32:11-36:44) would have reinforced a POSITA’s understanding that the claimed Active Agent, through this mechanism of action applicable to the various keratins, is operable across different keratins, especially for nails that had a “complete set of hair keratins” (EX2009, 2604).

59. Second, Wella contends that the ’225 Patent “fails to provide sufficient direction” for “treating different types of keratin substrates” because the choice of “water content” and “organic solvent content” (e.g., alcohol) can yield different effects on different substrates, where “applying treatments suitable for hair to a nail leads to unintended and often damaging consequences.” Pet., 28-29; EX1002, ¶¶ 117, 167. This does not address the claimed Active Agent’s ability to treat keratin across the various substrates by bonding to thiols. And with respect to excipients like “water” and “organic solvent[s]” (Pet., 28-29), the ’225 Patent provides extensive guidance with an enumeration of “[c]osmetically acceptable excipients,” including “water,” “alcohol,” and possible concentrations thereof. EX1001, 19:56-23:67 (“The formulations typically contain[] greater than one percent (wt) water.”).

I disagree with Wella's and Ms. Gallo's position that a POSITA, in possession of the claimed Active Agent, "would need a great deal of direction" for the mere selection of excipients and concentrations thereof or that the '225 Patent's list of excipients is inadequate to provide "any direction or guidance with respect to . . . application of the treatment formulation to the nail" without "unintended and often damaging consequences." Pet., 28-29; EX1002, ¶¶ 134-137. As even Ms. Gallo acknowledges, "*a POSA would know*" what "concentration" of these excipients to use for hair, skin, and nails to achieve the desired effects. EX1002, ¶¶ 83-86, 117.

60. In view of the above, these factors weigh in favor of enablement.

4. Nature of the Invention and Predictability of the Art

61. Wella contends that the "subject matter of the '225 patent invention is in part within the field of biology, specifically *in vivo* biology, and in part within the field of chemistry" and that "[i]nventions within the fields of chemistry and biology, especially *in vivo* biology, are unpredictable." Pet., 24-26; EX1002, ¶¶ 138-146. And Wella adds that because "the specification suggests the formulation . . . can contain up to 10 separate excipients/ingredients" that "must be properly optimized," making "a suitable formulation to treat nail keratin [would have been] very unpredictable." Pet., 24-26; EX1002, ¶ 142. I disagree.

62. At the outset, all of Wella's contentions regarding the alleged unpredictability stemming from the choice of "binding agent[]" characteristics—

including the “molecular weight,” “linkers,” and “reactive moieties” like “Michael acceptors, vinyl sulfones, vinyl sulfoximines, electrophilic moieties containing a leaving group, electrophilic thiol acceptors, or free-radical forming groups”—are *irrelevant* because the Challenged Claims *specify the Active Agent*, including its linker (1,6-hexanediamine) and reactive moieties (maleic acid, a Michael acceptor). Pet., 24-25; EX1001, Claim 1. That is, the ’225 Patent would not have required a POSITA to engage in the purportedly unpredictable design of the “binding agent” (Pet., 24-25), as it already provided that detail with the claimed Active Agent. And there would have been no unpredictability in this Active Agent’s ability to treat keratin, as—per the ’225 Patent and as explained in Section VIII.A.1—it did so by reacting with the keratin’s thiol groups through a thiol-Michael addition “to form covalent bonds.” EX1001, 10:57-61, 11:15-18, 11:33-12:10, 17:50-19:25. Ms. Gallo’s unsupported opinion that “a POSA would find it very difficult to predict the concentration of binding agent needed to provide effective crosslinking of the nail keratin” (EX1002, ¶ 144; Pet., 25) is inconsistent with the well-known and predictable nature of this kind of reaction, as “thiol-based Michael-type addition reactions ha[d] emerged as a widely employed strategy for covalent conjugation of proteins.” EX2002, 2.

63. Wella also maintains that the choice of “excipients” among the options set forth in the specification (EX1001, 19:56-23:67) would have been unpredictable,

but that is not credible. Excipients and their effects were well-known, so much so that they are named by what they do. *See* EX1001, 21:14-22:16 (“Surfactants are surface-active agents that are able to reduce the surface tension of water.”), 22:17-38 (“Emollient refers to a material that protects against wetness or irritation, softens, soothes, coats, lubricates, moisturizes, protects, and/or cleanses the skin.”), 22:39-51 (“Emulsifiers,” which stabilize emulsions), 22:52-23:11 (“preservatives . . . prevent microbial growth”), 23:12-23:28 (“conditioning agents,” such as to condition hair), 23:29-38 (“Diluents . . . dilute[] the binding agent.”), 23:39-23:53 (“viscosity modifying agents, such as viscosity increasing agents”), 23:54-61 (“Antioxidants”), 23:62-67 (“Opacifying agents . . . make [the formulations] opaque”); EX2004, 3. And, again, even Ms. Gallo acknowledges that “*a POSA would know*” what excipients to use and in what amount to achieve different effects for different keratin-containing substrates. EX1002, ¶¶ 83-86, 117.

64. Wella’s final contention that “a POSITA would effectively need to start from scratch to arrive at a method of treating keratin other than hair or skin”—specifically, “treatment of the nail”—is likewise not credible. Pet., 25-26. This is first highlighted by Ms. Gallo’s acknowledgement that the ’225 Patent’s disclosure is “sufficient” for a POSA “to make a composition comprising the claimed binding agent . . . and use it to treat the keratin of a person’s hair (and potentially skin)” (EX1002, ¶ 119)—with that knowledge, nail keratins treatments are hardly a jump,

as “nails are part of [the] skin” and the “nail plate contains . . . [a] complete set of hair keratins.” Pet., 25-26; EX2010, 1; EX2009, 2604. And as set forth above, the ’225 Patent provides the active ingredient of the claimed treatment, its mechanism of action that is applicable to keratin other than hair, and a list of suitable excipients. That is not “start[ing] from scratch.” Pet., 25-26. And I disagree with Ms. Gallo’s opinion that a POSITA “would find it difficult and unpredictable[] to select and prepare a formulation that would deliver the binding agent to the nail keratin most effectively” (EX1002, ¶ 144)—a POSITA, for example, would have been able to topically apply the claimed composition to the “hard nail plate” that contains the “keratin,” where others have found “positive reaction[s]” with compounds that bond to keratin thiols just as the claimed Active Agent would have. EX2008, 536-537; EX2014, 37, 49, 52 (“Sulfhydryl stains”—which are stains that bond with free thiols that are also called “sulfhydryl” groups—achieve “positive” reactions in nail); EX1001, 10:57-59. Indeed, others saw no difficulty applying a treatment “to a keratin material” in “nails,” among other keratin-containing substrates. EX2005, ¶¶ [0003], [0019], [0056], [0058], [0062].

65. This factor thus weighs in favor of enablement.

5. Quantity of Experimentation Necessary

66. Wella argues that “a POSITA would need to experiment thoroughly to arrive at a method of treating keratin other than in hair and skin” and, again, that a

POSITA “would need to essentially start from scratch in order to create a formulation effective at treating keratin” in nails. Pet., 26-27; EX1002, ¶¶149-153. I again disagree.

67. As I set forth in paragraph 64, Wella’s and Ms. Gallo’s position that a POSITA would “need to essentially start from scratch . . . [to] treat[] nail keratin” (EX1002, ¶ 149; Pet., 28) neglects the ’225 Patent’s disclosure of the claimed Active Agent (EX1001, Abstract, 7:61-62, 8:20-24, 11:15-18, 12:1-10, col. 16), its mechanism of action (“react[ing] with thiols to form covalent bonds” via thiol-Michael-addition chemistry) that is applicable to the various keratins (including nail keratin) that all have “a large amount of cysteine residues, which have a thiol group (-SH)” (EX2012, 449; *see also* EX1001, 10:57-61, 11:15-18, 11:33-12:10, 17:50-19:25), and even a list of “[c]osmetically acceptable excipients” (EX1001, 19:56-23:67). Indeed, this position is not credible in view of Ms. Gallo’s acknowledgement that the ’225 Patent “includes sufficient disclosure for a POSA to make a composition comprising the claimed binding agent of claim 1 and use it to treat the keratin of a person’s hair (and potentially skin),” as a POSITA knew that “nails are part of [the] skin” and the “nail plate contains . . . [a] complete set of hair keratins.” EX2010, 1; EX2009, 2604 EX1002, ¶119. Knowledge regarding treating hair keratins was readily applicable to nail keratins.

68. Wella maintains that “[b]ecause nails are thicker and more rigid than hair or skin, using the method as prescribed by claim 1 promises no guarantee that the formulation will actually reach or contact keratin in a nail.” Pet., 26-27; EX1002, ¶¶ 144, 146-147, 150. This does not reflect that “extensive”—or even any—experimentation would have been required. Pet., 26-27. As I explained in paragraph 64, nail keratins were contained in the external “nail plate,” rendering them readily treatable with a topical application, which is underscored by others finding “positive reaction[s]” with keratin thiols as the claimed Active Agent would have had. EX2008, 536-537; EX2014, 37, 49, 52; EX1001, 10:57-59. This, again, is further evidenced by others seeing no difficulty in applying a treatment “to a keratin material” in “nails,” among other keratin-containing substrates. EX2005, ¶¶ [0003], [0019], [0056], [0058], [0062].

69. Wella finally refers back to “the many components enumerated in [its analysis of] Factors 4 and 7” (Section VIII.C.4) as purportedly “requir[ing] extensive experimentation and optimization” to “properly treat the nail.” Pet. 26-27. However, as set forth in Section VIII.C.4, the ’225 Patent already takes care of the hard part of that “extensive experimentation and optimization” with its specification of the claimed Active Agent (EX1001, Abstract, Claim 1), which at most would have left a POSITA to decide which, if any, auxiliary excipients like “water” and “alcohol” to include with the Active Agent (*see, e.g.*, EX1001, 19:56-23:67). And,

as set forth in Section VIII.C.4, excipients and their effects were well-understood, undermining Wella's contention that "extensive experimentation and optimization" would have been required. EX1001, 19:56-23:67 (describing their effects); EX2004, 3. This is especially because, as Ms. Gallo opines, "*a POSA would know*" what excipients to use and in what amount to achieve different effects for different keratin-containing substrates, evidencing that little to no experimentation would have been required for such an excipient selection. EX1002, ¶¶ 83-86, 117.

70. This factor thus weighs in favor of enablement.

6. Weighing the Wands Factors Supports Enablement

71. Weighing all of the factors set forth above in Sections VIII.C.1-5, the specification of the '225 Patent would have enabled a POSITA to make and use the claimed methods without undue experimentation. As set forth above, Wella's position that "the scope in the '225 patent is expansive" (Pet. 29-30) neglects that the Challenged Claims recite *one* specifically defined active ingredient—the Active Agent—to treat a specifically-defined class of proteins ("keratin of a person") via a mechanism of action that applies to all such proteins. Section VIII.C.1. The '225 Patent thus did the hard part. Wella's position that there "is not a single example or even suggestion or vague inkling that encompasses keratin in nails or any other parts of the body" (Pet. 30-31) does not address a POSITA's understanding that the described mechanism of action for the claimed Active Agent would have been

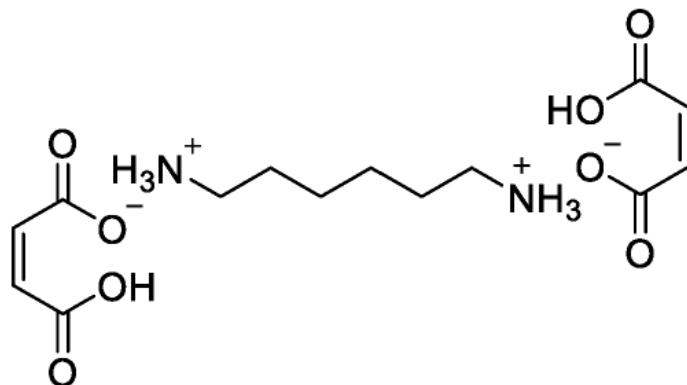
applicable to all keratins, which have “a large amount of cysteine residues, which have a thiol group (-SH)” (EX2012, 449) that the claimed Active Agent can interact with (EX1001, 10:57-59), as well as a POSITA’s knowledge that nail keratin contained *the same keratin found in hair* (EX2009, 2604). Section VIII.C.3. This leaves Wella with its assertion that the claims’ openness to inactive excipients in the composition like “water” and “alcohol” would require an “unpredictable” selection through “undue experimentation.” Pet., 30-31. But a POSITA’s intimate familiarity with excipients like “water” and “alcohol” and their effects, as even set forth in the ’225 Patent’s specification (EX1001, 19:56-23:67), undercuts any contention that their selection was “unpredictable” or would require “undue experimentation.” Sections VIII.C.2, VIII.C.4, VIII.C.5. The ’225 Patent’s disclosure thus would have enabled a POSITA to perform the full scope of the claimed methods without undue experimentation, including the treatment of nail keratin.

IX. THE SPECIFICATION REASONABLY CONVEYS TO A POSITA THAT THE INVENTORS POSSESSED THE CLAIMED METHODS

72. I understand that Wella contends that “[t]he ’225 patent claims fail for written description,” relying on Ms. Gallo’s opinions in paragraphs 94-106 of her declaration. Pet., 31-39. Under the standard set forth in paragraph 20, I disagree.

73. To begin, the ’225 Patent’s specification literally describes the subject matter of independent claim 1, including in its original claims:

A method of treating keratin of a person is disclosed. The method includes contacting the keratin with a composition comprising a compound having a chemical structure of



EX1001, Abstract; EX1003, 47, 49/231. Despite this literal disclosure, I understand that Wella maintains that claim 1 is unsupported because it “purports to cover ‘a method of treating [all] keratin of a person’” and the ’225 Patent purportedly “is silent as to methods of treating any other form of keratin in a person’s body besides the hair and skin.” Pet., 33-36. While Wella lists keratin in “nails, eye lashes², and internal organs among other body parts” as examples of keratin beyond that in “hair and skin,” Ms. Gallo identifies only one purportedly-unsupported keratin treatment encompassed by claim 1: “treating nail keratin.” EX1002, ¶¶ 95-96, 102-104. Wella and Ms. Gallo are mistaken—the ’225 Patent’s specification reasonably

² Eye lashes are hair, so Wella’s implication that “eye lashes” are something other than “hair” is wrong.

conveys possession of treating a person's keratin with the claimed Active Agent, including keratin in nails.

A. Nails Are Part of the Skin and Contain Hair Keratin

74. First, Ms. Gallo's acknowledgement that there is support for "methods of treating keratin found [] in human hair and skin" (EX1002, ¶¶ 102-103) confirms that the '225 Patent's specification reasonably conveys possession of the nail keratin treatments encompassed by claim 1. As explained above in Section VIII.A.2, a POSITA knew that "nails are *part of [the] skin*" and that "[h]air *keratins* are . . . found abundantly in hair *and fingernails*." EX2010, 1; EX2007, 585; *see also* EX2008, 536 ("The nail is an infolding of skin that occurs at the terminal end of each digit."); EX2009, 2604 (The "nail plate contains ... [a] complete set of hair keratins"). Accordingly, the '225 Patent's disclosure that its "compounds [] interact with keratin" that can be "in the hair" and "skin" reasonably conveys possession of treating keratin in part of the skin—nails—that includes the keratin that is also contained in hair. EX1001, 2:17-31, 3:41-44. The '225 Patent's failure to use the word "nail" or include a "nail" example does not show otherwise, as Wella and Ms. Gallo contend (Pet., 33-34; EX1002, ¶¶ 95-100)—in view of a POSITA's knowledge that nails included hair keratin and were part of the skin, the '225 Patent's hair and skin disclosures support, rather than detract from, a POSITA understanding

that the inventors possessed nail keratin treatments encompassed by the described “method of treating keratin” (EX1001, Abstract).

75. Furthermore, hair and skin keratins encompass and thus are representative of the two classes of keratins. “All [] keratins . . . share common protein-structural characteristics” and are “classified as ‘hard’ or ‘soft,’” with “softer keratin ha[ving] less sulfur.” EX2013, 705; EX2012, 449. “[N]ails . . . and hair are composed of ‘hard’ keratins” and other parts of “the outermost layer of the skin” contain “almost exclusively” “[s]oft keratin.” EX2012, 449; EX2007, 585. The ’225 Patent’s illustrative treatments of keratin in “hair” and “skin” (*see, e.g.*, EX1001, 3:41-46, 10:57-61) thus illustrates the treatability of both classes of keratin, further evidencing that they are representative of treating “keratin of a person.”

B. The ’225 Patent Describes a Common Mechanism of Action for the Active Agent to Treat Keratins Generally

76. Second, the ’225 Patent reasonably shows possession of using the claimed Active Agent to treat keratins generally—which are a “family of [] proteins” that “share common protein-structural characteristics” (EX2013, 707)—in its description of a common feature of keratins that renders the Active Agent applicable to the treatment thereof, as detailed above in Section VIII.A.1: their “free thiols” that are responsible for their “disulfide bonds,” where the Active Agent’s reactive moieties (maleic acid) “react with thiols [of the keratin] to form covalent bonds” and thereby repair broken disulfide bonds. EX1001, 1:34-43, 1:51-2:31, 3:7-8, 3:15-17,

3:30-52, 4:8-13, 7:56-58, 8:20-25, 10:57-59, 11:15-18, 11:33-12:10, col. 16, 17:51-19:53; EX2012, 449; EX2007, 586. With this understanding, a POSITA reading the '225 Patent's disclosure knew—consistent with the patent broadly describing a “method of treating keratin of a person” (EX1001, Abstract)—that it applied to keratin generally, which contained the “thiols” that the claimed Active Agent's reactive moieties bonded with to treat keratin. EX1001, 10:57-61 (“The binding agent contains at least two reactive moieties that react with thiols to form covalent bonds,” where reactions “with a thiol group in the hair or on the skin to form a stable covalent bond” are exemplary but non-limiting.). Ms. Gallo acknowledges that the '225 Patent's compounds work by reacting with “the thiol residues that are part of the keratin,” and while she notes that the illustration is for “hair,” she does not—and cannot—show that the mechanism of action is different for other keratins. EX1002, ¶ 99.

77. The Active Agent's common mechanism of action for keratins generally thus further shows possession of treating keratin with the claimed Active Agent. Despite Wella's contrary assertion, the '225 Patent did not leave a POSITA with “only a research plan . . . to explore the unknown contours of the claimed genus” (Pet., 34)—claim 1 recites a specific compound (maleic acid, 1,6-hexanediamine) to treat a known, specific class of proteins (keratin) and the '225 Patent explains a

mechanism of action for that treatment (binding to keratin free thiols) that applied to the “keratin of a person” as claimed.

C. Unrecited Excipients Do Not Show Lack of Possession

78. I understand that Wella also maintains that “claim 1 fails for written description” for purportedly “broadly claim[ing] any composition involved in *treating* keratin” despite claim 1 specifically reciting one of the ’225 Patent’s keratin-treating active agents (maleic acid, 1,6-hexanediamine). Pet., 35-36. According to Wella, this is because claim 1 does not specify excipients like “water.” Pet., 35-36. A POSITA would not have shared Wella’s view.

79. Consistent with the ’225 Patent’s disclosure that “excipients”—the “constituents of a pharmaceutical form apart from the active substance” (EX2004, 3)—are optional, a POSITA would have understood that the ’225 Patent’s inventors possessed keratin treatments using the claimed Active Agent without being limited to specific excipients that are auxiliary to the Active Agent. EX1001, 7:61-64 (“The binding agents *can be* combined with one or more pharmaceutically acceptable carriers and/or excipients”), 19:56-58 (“The formulations *typically*”—not always—“contain one or more cosmetically acceptable excipients”); EX1003, 47/231 (original claim 1 not excipient-limited). Wella’s position that the ’225 Patent’s specification “fails to describe a sufficient number of species” to show possession of claim 1’s excipient-generic keratin treatment (Pet., 35-36) misses both the

optionality of the excipients and the '225 Patent's extensive disclosure of representative excipients usable in its formulations (EX1001, 19:56-23:67), including surfactants (EX1001, 21:14-22:16), emollients (EX1001, 22:17-38), emulsifiers (EX1001, 22:39-51), preservatives (EX1001, 22:52-23:11), conditioning agents (EX1001, 23:12-23:28), diluents (EX1001, 23:29-38), viscosity modifying agents (EX1001, 23:39-23:53), antioxidants (EX1001, 23:54-61), and opacifying agents (EX1001, 23:62-67).

80. The only unrecited excipient Wella identifies as purportedly required to show possession of claim 1's keratin treatment is "water" (Pet., 35-36), where—accordingly to Wella—there is an "absolute need for water in a formulation meant to moisturize and condition hair and skin" such that a claim encompassing "treatments with no water content . . . fails for written description." Pet., 35-36. There are a number of issues with Wella's position. First, Wella's position is based on the false premise that claim 1's "formulation [is] meant to moisturize and condition hair and skin" (Pet., 35-36)—claim 1 recites "treating keratin" (such as by "reacting with a thiol" of keratin to "rebuild latent disulfide bonds"), not moisturizing and conditioning hair and skin. EX1001, Claim 1, 3:30-33, 7:56-58, 8:20-22, 10:57-59. Thus, whether there was an "absolute need for water" to "moisturize and condition hair and skin" (Pet., 35-36) has no bearing on whether the '225 Patent's specification reasonably conveys possession of claim 1, which does

not require that functionality. Second, the portion of the '225 Patent that Wella cites for its position that there is an “absolute need for water” does not support Wella’s position. Pet., 35-36. That portion of the specification teaches that “[w]ater is the *preferred diluent*.” EX1001, 23:29-35. As set forth above in paragraph 79, the '225 Patent describes that “diluent” like “water” is one of its *optional* “excipients,” and even then, water is a “preferred”—not required—diluent. EX1001, 7:61-64, 19:56-58, 23:29-35. This belies Wella’s argument that “a treatment with *no water whatsoever* is specifically not described by this specification.” Pet., 36.

81. Accordingly, the '225 Patent’s specification reasonably conveys possession of claim 1 without specifying excipients like water.

D. Dependent Claims 2-12 and 15-17 Are Supported

82. Wella and Ms. Gallo do not address the impact of the additional limitations recited in dependent claims 2-12 and 15-17 on the written description inquiry, with Ms. Gallo maintaining that “these claims [] lack written description for the same reasons as claim 1.” Pet., 33-39; EX1002, ¶ 105. Wella’s and Ms. Gallo’s positions against these claims thus fail for the same reasons set forth above for independent claim 1.

X. A POSITA WOULD HAVE BEEN ABLE TO ASCERTAIN THE SCOPE OF THE CLAIMS WITH REASONABLE CERTAINTY

83. I understand that Wella, relying on Ms. Gallo’s opinions in paragraphs 158-171 of her declaration, contends that the terms “keratin of a person” and

“treating” in claim 1 of the ’225 Patent are “vague, ambiguous, and indefinite.” Pet., 40-42. I disagree.

A. “Keratin of a Person”

84. A POSITA would have been able to ascertain the scope of “keratin of a person” with reasonable certainty. As Wella’s own evidence shows—and what Ms. Gallo acknowledges—a POSITA knew what “keratin of a person” was: it was a “type of protein found on epithelial cells.” EX1004; EX1002, ¶ 161; *see also* EX2012, 449-452 (describing that “[k]eratin is a structural protein found in the integument (outer covering) in vertebrates” and showing “the molecular structure of” different forms of keratin). Because “keratin of a person” was a known type of protein, a POSITA would have been able to ascertain the scope thereof with reasonable certainty.

85. Wella argues that there is “lack of clarity as to which keratin-rich substrate is intended” because “[k]eratin ‘of a person’ encompasses more than just keratin in hair or keratin in nails” and “*all* keratin-rich substrates cannot be treated using one universal method.” Pet., 40-41. As support, Wella cites to Ms. Gallo’s opinion that a POSITA “would just have to take a guess at which keratin-containing substrate they believe the claimed invention is directed to” and that “the method of treatment” for different keratins “is different.” Pet., 40-41. EX1002, ¶¶ 147, 150, 161. Thus, per Wella, if claim 1’s “keratin” is not “synonymous with ‘keratin in the

hair of a person,” it “is vague, ambiguous, and indefinite.” Pet., 40-41. Wella and Ms. Gallo are mistaken.

86. With its recitation of “keratin of a person” that is “contact[ed] . . . with a composition comprising” the Active Agent, claim 1’s treatment—to a POSITA—encompasses contacting keratin of a variety of substrates, not just “keratin in the hair of a person” (Pet., 40). The claimed Active Agent’s common mechanism of action for treating keratin (Sections VIII.A and IX.B) reinforces a POSITA’s understanding that the claimed, treated “keratin of a person” encompasses keratin across multiple substrates. This broader applicability of the claimed treatment does not mean that the claim is ambiguous, as Wella argues. As set forth in paragraph 84, a POSITA knew the different forms of “keratin of a person” and thus would have been able to ascertain with reasonable certainty whether “keratin of a person”—whether in the hair or another substrate—is “contact[ed]” with a “composition comprising” the Active Agent, as claimed. That a “formulation needs to be appropriate for the binding agent as well as optimized for the specific substrate” as Ms. Gallo contends (EX1002, ¶¶ 147, 150) does not speak to the clarity of the claims. Consistent with the claimed treatment’s applicability to “keratin of a person” across multiple substrates, the claimed treatments leave open implementational details for applying the claimed Active Agent—like those Ms. Gallo identifies (EX1002, ¶ 147)—which evidences the broader applicability of the treatment, not ambiguity.

B. “Treating”

87. Wella contends that the term “treating” is “too broad to clearly inform a POSITA what the metes and bounds of the claims are” because “the treatment may comprise *any additional components*” beyond the claimed Active Agent and the Specification “provides no concrete boundaries for what *must* and *must not* be included” with the Active Agent “for the treatment to be effective.” Pet., 41-42. Wella’s focus again is on claim 1 not specifying “excipients” like “water” that Wella and Ms. Gallo maintain “are necessary for the method of ‘treating’ to even work,” with Ms. Gallo maintaining that “[t]here is nothing in challenged claim 1 that informs a POSA with any certainty what the treatment is, why any alleged ‘treatment’ would provide a net positive to the person, and what the treatment is directed to.” Pet., 41-42; EX1002, ¶¶ 163-170. Wella and Ms. Gallo again mistakenly characterize the breadth of claim 1’s treatment as ambiguity.

88. Consistent with the ’225 Patent’s disclosure of wide range of “excipients” like “water” that can—but, contrary to Wella’s contention, need not—accompany the claimed Active Agent, the claims’ omission of excipient details means that they encompass treatments that can employ a variety of excipient combinations. EX1001, 7:61-64 (“The binding agents *can be*”—not must be—combined with one or more pharmaceutically acceptable carriers and/or excipients”), 19:56-23:67 (“The formulations *typically*”—not always—“contain one

or more cosmetically acceptable excipients”). This does not mean that the claimed treatments are ambiguous, just that they are open to a variety of implementations that can include, for example, a variety of excipients. Wella’s and Ms. Gallo’s implication that certain treatments would be inoperable without certain excipients like “water” (Pet., 40-41; EX1002, ¶¶ 164-166) again fails to speak to the clarity of the claims and nevertheless misses that, as explained in Section VIII.B, choosing excipients to accompany the claimed Active Agent to achieve a desired result (e.g., based on the substrate to which the composition is applied) would have been well within a POSITA’s skillset. And Ms. Gallo’s opinion that there may be “additional end results of treatment” that can be “substrate-specific” (EX1002, ¶ 167) also does not mean that the claimed “treating” is ambiguous, just that—if Ms. Gallo’s opinion is accepted—the “treating” allows there to be a variety of “additional end results.”

89. At bottom, claim 1—and thus its dependent claims—recites “treating keratin of a person” at least by “contacting the keratin with a composition comprising” the Active Agent that, as the ’225 Patent explains, can treat keratin by “repairing disulfide bonds” (e.g., by “react[ing] with thiols [of the keratin] to form covalent bonds”). EX1001, Abstract, 3:41-44, 4:8-13, 8:20-25, 10:57-61, 11:15-18, 11:33-12:10, 17:51-19:53, col. 16. There is nothing ambiguous about that.

XI. CONCLUSION

90. All statements made herein of my own knowledge are true, all statements made herein on information and belief are believed to be true, and these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001.

Dated: 02/12/2026

RR Wickett
Dr. Randall Wickett

ATTACHMENT A

RANDY R. WICKETT, Ph.D.

EDUCATION:

Ph.D., biophysics, Oregon State University, Corvallis Oregon, 1973

B.A., chemistry, Western Washington State College, Bellingham Washington, 1968

WORK EXPERIENCE:

7/93-Present: President R. Randall Wickett Consulting Services, providing services to the Personal Care and Pharmaceutical Industries on claim support, research guidance, test design, clinical monitoring, custom formulation and technical training in skin and hair care science and technology, experienced expert witness in patent and claim support litigation including trial testimony. References are available on request.

1/14-Present: Professor Emeritus of Pharmaceutics and Cosmetic Science. University of Cincinnati College of Pharmacy

9/98-2013: Professor of Pharmaceutics and Cosmetic Science, University of Cincinnati, College of Pharmacy: In charge of graduate program in skin pharmaceutics and cosmetic science.

7/91-9/98: Associate Professor of Pharmaceutics and Cosmetic Science, University of Cincinnati, College of Pharmacy.

9/88-7/91: Research Associate, Dermal Research Department, S.C. Johnson Wax, Racine WI. In charge of clinical and biophysical research group, conducting *in vitro* and *in vivo* testing for guidance of product development and advertising claim support in skin and hair care.

10/85-9/88: Senior Scientist, Department of Dermal Research, S.C. Johnson Wax, Racine WI: Responsible for biophysical testing of skin and hair care product efficacy for research guidance and advertising claim support.

7/74-10/85: Staff Scientist, Procter & Gamble, Cincinnati OH: Basic and applied research on skin and hair.

9/72-6/74: Post-Doctoral Fellow, University of Minnesota Minneapolis MN: Research on protein conformational dynamics.

PROFESSIONAL AWARDS AND HONORS:

Maison G. deNavarre Medal Award from the Society of Cosmetic Chemists (SCC), awarded December 1997 and December 2021. This is the Society's highest honor, awarded for technical contributions to cosmetic science.

Robert A. Kramer Lifetime Service Award -Society of Cosmetic Chemists 2024.

Lifetime Achievement Award from the International Society for Biophysics and Imaging of the Skin, presented in 2024.

Appointed a Fellow of the International Federation of Societies of Cosmetic Chemists, 2023.

International Journal of Cosmetic Science Award for best paper published in the Journal in 2011 (with M. Visscher and M. Robinson)

Appointed an International Corresponding Member of the Chilean Academy of Pharmaceutical Sciences, August 7, 2009

Society of Cosmetic Chemists Merit Award for distinguished contributions, achievement and service to the Society December 7, 2007

Society of Cosmetic Chemists 2001 Literature Award for outstanding contributions to the cosmetic science literature

International Flavors and Fragrances Award for best paper presented to the Society and published in the Journal of the Society of Cosmetic Chemists during 1998 (With A Shah and S. Mukerjee).

Elected a Fellow of the Society of Cosmetic Chemists, September 1996

Joseph P. Ciaudelli award for the best paper on hair care technology, published in the Journal of the Society of Cosmetic Chemists during 1996 (with M. Manuszak and E. Borish).

International Flavors and Fragrances Award for best paper presented to the Society and published in the Journal of the Society of Cosmetic Chemists, 1996 (with M. Manszak and E. Borish).

Shaw Mudge Award for best paper presented at the SCC Annual Scientific Seminar, May 1996 (with D. Imbert and G. Kasting, paper presented by D. Imbert).

Dragoco Award for best paper presented at the SCC Annual Scientific Meeting, December 1994 (with A. Warrier, R. Harper, J. Bowman and A. Kligman, paper presented by R. Wickett).

SCC Ohio Valley Chapter Award for best scientific paper presented to the SCC Ohio Valley Chapter during 1991.

International Flavors and Fragrances Award for best paper presented to the SCC and published in the Journal of the Society of Cosmetic Chemists during 1983.

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PROFESSIONAL SERVICE:

President: Society of Cosmetic Chemists, December 2010 – December 2011

Vice President: Society of Cosmetic Chemists, December 2009-December 2010

Vice President Elect: Society of Cosmetic Chemists, December 2008 December 2009

Chairman: International Society for Bioengineering and the Skin, March 2000-October 2005

Editor: Journal of the Society of Cosmetic Chemists, January 1991- December 1997.

Committee on Scientific Affairs: Society of Cosmetic Chemists, 2000-2004

Education Advisory Board: Society of Cosmetic Chemists 2000-2003

US Program Convenor: International Society for Bioengineering and the Skin now International Society for Biophysics and Imaging of the Skin. (ISBS), 1988 to 2018

Editorial Committee: Journal of the Society of Cosmetic Chemists, Skin Research and Technology, International Journal of Cosmetic Science, Romanian Society of Cosmetic Chemists Magazine

Program Chairman: Ohio Valley Chapter of the SCC, 1993-1994, 1996-1998.

50th Anniversary Committee: Society of Cosmetic Chemists, 1995.

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INVITED PRESENTATIONS

75 Years of Scientific Innovation and Advancements and Future Predictions, Society of Cosmetic Chemists Annual Meeting, New York NY, December 13, 2021

Current Trends in Hair and Skin Care Beauty Products, Chiang Mai University October 10, 2019

Use of Biomarkers and Biophysical Measurements to Guide the Development of Innovative Beauty Care Products, Keynote Address Cosmetic & Beauty International Conference, Chiang Rai Thailand October 9, 2019.

Anti-Aging Cosmetics, Thailand Society of Cosmetic Chemists, Chiang Mai Thailand, November 2, 2018.

Human Skin Anatomy and Physiology in Health and Disease, Dermatological Drug Products, Development and Regulatory Considerations, Workshop, American Association of Pharmaceutical Sciences, San Diego CA, November 11-12, 2017.

Combining Biomarkers and Instrumental Measurements in Skin Research, Keynote address 40th Anniversary meeting of the South African Society of Cosmetic Chemists, Johannesburg South Africa September 13-14 2017

Postnatal development of infant skin function, 40th Anniversary meeting of the South African Society of Cosmetic Chemists, Johannesburg South Africa September 13-14, 2017

Effects of season on stratum corneum barrier function and skin biomarkers, Southwest Chapter Society of Cosmetic Chemists, Dallas TX, May 11, 2017

Latest methods for evaluating cosmetic product effects on skin, including biomarkers and instrumentation, Chiang Mai University, Chiang Mai Thailand, November 7, 2016

Role of structural and sebaceous lipids in skin health, American Oil Chemists Society Meeting, Salt Lake City, UT, May 2-4, 2016

Cytokines and Structural Proteins as Biomarkers of Skin Health, Workshop on Omics, In Cosmetics Paris France April 12, 2016

Skin Structure and Device Interfacing, Skin for Engineers Workshop, Miami FL January 19-20, 2016

Innovative Actives and Current Trends in Cosmeceuticals, Faculty of Pharmacy, Chiang Mai University, Chiang Mai Thailand, November 6, 2015

Surfactants and human skin: Perspectives from 40 years of skin research, Joint meeting of the American Oil Chemists Society and the Society of Cosmetic Chemists, Orlando FL, May 4-6, 2015

Variable Responses to Skin Irritants, Ohio Valley Chapter of the Society of Cosmetic Chemists, Cincinnati OH, February 18, 2015

Topical Delivery Fundamentals: Mini-Breakfast Seminar, Society of Cosmetic Chemists Annual Scientific Meeting, New York NY, December 12, 2014

Mechanical and Optical Evaluation of Skin, World Congress of International Society for Biophysics and Imaging of the Skin, Mystic CT, June 2, 2014

Reflections on 40 years in Skin Science, Ohio Valley Chapter of the Society of Cosmetic Chemists, Cincinnati OH, April 16, 2014

Skin Barrier to Cosmetic Ingredient Delivery: Symposium-Moving Forward to Skin Care Cosmetic Innovation: Bangkok Thailand, February 13, 2014

Skin Measurements, in House, in a CRO or in the "Real World", Key Note Address, California Chapter of the Society of Cosmetic Chemists Suppliers Day, Los Angeles CA, September 24-25, 2013

Biochemistry and Biophysics of the Skin, Mini-Breakfast Seminar, Society of Cosmetic Chemists Annual Scientific Seminar, St. Louis MO, June 6-7, 2013

Cosmeceuticals: What are they and how do they work? Perspectives in Percutaneous Penetration, 13th International Conference, La Grande Motte France April 10-14, 2012

Development and Testing of Natural Cosmeceuticals, Keynote Lecture, International Federation of Society of Cosmetic Chemists Conference Bangkok Thailand, December 12-14, 2011

Skin Research in the "Real World", US symposium of the International Society for Biophysics and Imaging of the Skin, Tampa FL April 7-9, 2011

New Dimensions in Personal Care: Harnessing the Synergy between Dietary Nutrients and Cosmeceuticals, Conference on Natural and Functional Ingredients, Bangkok Thailand March 16, 2011

Future Trends for Development and Testing of Cosmeceuticals from Nature, Keynote Lecture 3rd International Conference of Natural Products for Health and Beauty, Bangkok Thailand March 16-18, 2011

The Future of Non-invasive testing of skin care products, 3rd International Conference of Natural Products for Health and Beauty, Bangkok Thailand March 16-18, 2011

Measurement Technology Transfer between Medical and Cosmetic Applications, Technology Transfer Conference of the New York Society of Cosmetic Chemists, Newark NJ, October 20, 2010

The Future of Noninvasive Measurements for Cosmetic Claim Support, Annual Scientific Seminar of the California Society of Cosmetic Chemists, Los Angeles CA, October 7, 2010

Mechanical and Surface Properties of Skin, World Congress of the International Society for Biophysics and Imaging of the Skin Buenos Aires Argentina, September 24-26, 2010

Influence of TNF- α polymorphism -308 on Neurosensory Response and Irritant Dermatitis, Twin Cities Chapter of the Society of Cosmetic Chemists, Minneapolis MN April 20, 2010

Measuring Cosmetic Efficacy, Conference on Wisdom and Research Application in Thai Herbal Cosmeceuticals, Bangkok Thailand, December 17-18, 2009

Current Research in Cosmeceuticals, Conference on Wisdom and Research Application in Thai Herbal Cosmeceuticals, Bangkok Thailand, December 17-18, 2009

Neonatal Skin Maturation – *Vernix Caseosa* and Natural Moisturizing Factor, International Society for Biophysics and Imaging of the Skin, Besancon France September 9-12, 2009

Effects of Hand Hygiene Procedures and Aggressive Lotion Intervention on Irritant Dermatitis in Health Care Workers in the “Real World”, Chilean Academy of Pharmaceutical Sciences, University of Chile, Santiago Chile August 17th 2009

Measuring Cellulite, 34th International Meeting of the Chilean Society of Cosmetic Chemists, Santa Cruz, Chile August 14-16, 2009

Basic Bioengineering Techniques for Skin Measurement, 34th International Meeting of the Chilean Society of Cosmetic Chemists, Santa Cruz, Chile August 14-16, 2009

Skin Rejuvenation from a Scientific Perspective, ENSAS-Estonian Dermatological Society Meeting, Tallinn Estonia, May 8, 2009

Effect of Lotions and Creams on Irritant Dermatitis in Health Care Workers, Southeast Chapter Society of Cosmetic Chemists, Memphis TN April 29, 2009

Mechanical Properties of Skin, International Society for Biophysics and Imaging of the Skin, Dallas TX, March 18-21 2009

Influence of Dressings on Barrier Repair: Effects on Biophysical Measurements and Natural Moisturizing Factors International Society for Biophysics and Imaging of the Skin, Dallas TX, March 18-21 2009

Oxidative Stress and Skin Aging, Bruno Werdleman Foundation Lecture, Department of Chemistry, Chiang Mai University, Chiang Mai Thailand December 22, 2008

Effect of oral intake of choline-stabilized orthosilicic acid on hair tensile strength and morphology in women with fine hair, 2nd International Conference of Natural Products for Health and Beauty, Phayao Thailand December 17-19 2008

Molecular Biology of Oxidative Stress in Photoaging of Skin, Society for Free Radicals Thailand Conference, Chiang Mai Thailand December 16, 2009

Racial and ethnic variations in Skin Properties and Response to Irritant, Formulating for Diversity Fall Technical Symposium, Midwest Chapter Society of Cosmetic Chemists, Chicago IL October 17, 2008

Vernix Caseosa, The Natural Moisturizer of a New Born Baby's Skin, Symposium in honor of Professor Ubonthip Nimminent, Chulalongkorn University Bangkok Thailand August 1-2 2008

Clinical Studies of Anti-aging products, "Symposium on the Evaluation of Cosmetic Products: Antiaging and Hair care Products", Bangkok Thailand September 6-7, 2007

Measuring Skin Irritation, "Symposium on the Evaluation of Cosmetic Products: Antiaging and Hair care Products", Bangkok Thailand September 6-7, 2007

Evaluating Hair, "Symposium on the Evaluation of Cosmetic Products: Antiaging and Hair care Products", Bangkok Thailand September 6-7, 2007

Measurement of Cellulite, 1st Symposium on Cosmetic and Health Innovations, Bangkok Thailand, May 26-27, 2007

Skin Pigmentation and Skin Lightening: Overview and Results with Deoxyarbutin and its Second Generation Derivatives, 1st Symposium on Cosmetic and Health Innovations, Bangkok Thailand, May 26-27, 2007

Structure and Function of the Epidermal Barrier, Back to Basics Skin care Symposium, Ohio Valley Society of Cosmetic Chemists, April 18, 2007

Electrical Measurements on Skin, International Society for Skin Imaging and Biophysics Meeting, Atlanta GA October 12-14, 2006

Effect of Weight Loss on Cellulite Severity, 20th Brazilian Congress on Cosmetology, San Paulo Brazil April 18-20, 2006.

Skin Color and Skin Lightening, Overview and results with a new skin lightening agent, Asociación Argentina de Químicos Cosméticos meeting, Buenos Aires Argentina, April 17, 2006

Function and analysis of skin's natural moisturizers, Asociación Argentina de Químicos Cosméticos meeting, Buenos Aires Argentina, April 17, 2006

Biochemical and Biophysical Studies of Skin's Natural Moisturizers, COSCEM 2005, Johannesburg, South Africa, October 5-6, 2005

Comparing African American and European American Skin: Biophysical Properties and Response to Irritant, 2nd World Congress on Non-Invasive Methods and the Skin, Philadelphia PA, September 29-October 1, 2005

Cutaneous Biometrology in Neonatal Medicine, Symposium in Honor of Pierre Agache, International Association of Cosmetic Dermatology Meeting, Paris France, July 3-5, 2005

Permanent Waving and Depilation, Society of Cosmetic Chemists Annual Scientific Seminar, Las Vegas, NV, June 2-3, 2005.

Bioengineering advances in the analysis of cellulite, Congress on Bioengineering and Biometrics of Skin and Hair, San Paulo Brazil, July 25,26 2004.

A new method for biochemical skin evaluation, Congress on Bioengineering and Biometrics of Skin and Hair, San Paulo Brazil, July 25,26 2004.

Basic Skin Evaluation Methods, Society of Cosmetic Chemists Annual Scientific Seminar, Uncasville CT, May 7-8, 2004.

Hair Structure, Chemistry and Product Evaluation, Symposium on Evaluation of Hair Care Products Chulalongkorn University, Bangkok Thailand, December 22-23, 2003

Basics of Skin Structure, Society of Cosmetic Chemists Annual Meeting, New York NY Dec 4-5 2003.

Basic Research on Ethnic Hair, to Second International Symposium on Ethnic Hair and Skin, Chicago IL, September 19-21, 2003

Bioengineering Evaluations of Exogenous and Endogenous Moisturizers, Midwest Chapter of the Society of Cosmetic Chemists, Chicago IL March 11, 2003

Skin color measurements, Symposium on Evaluation of Cosmetic Products, Chulalongkorn University, Bangkok Thailand, December 19-20, 2002

Use of Bioengineering Methods in Product Efficacy Studies, Symposium on Evaluation of Cosmetic Products, Chulalongkorn University, Bangkok Thailand, December 19-20, 2002

Electrical Measurements of Skin, International Society for Bioengineering and the Skin Workshop, Baltimore MD., October 24, 2002.

Current Research in Skin Moisturization: International Cosmetic Expo. Miami FL February 21, 2002.

Cosmetic Science Education at the University of Cincinnati, Naresuan University, Phitsanulok Thailand, October 13, 2001

Mechanisms of Skin Moisturization, Conference on Cosmetic Science, Mahidol University Bangkok Thailand, October 12, 2001

Skin Bioengineering and Biochemistry, Conference on Cosmetic Science, Mahidol University Bangkok Thailand, October 11, 2001

Overview of Skin Science Research at the University of Cincinnati, Providence University, Taichung, Taiwan, September 21, 2001

Recent Studies of Stratum Corneum Barrier Formation and Homeostasis, Taipei Medical University, Taipei Taiwan, September 20, 2001

Bioengineering evaluation of the water handling capabilities of stratum corneum *in vivo*, Creation and Hope, IFSCC International Conference, Taipei, Taiwan, September 17-19, 2001

Non-invasive evaluation of stratum corneum function: Fifth Romanian International symposium on Cosmetic and Flavour Products: Iasi Romania, May 29-June 1, 2001

Skin Biochemistry, Society of Cosmetic Chemists Annual Scientific Seminar New Orleans, LA, May 9, 2001.

Use of the Moisture Accumulation Test to Assess Skin Breakdown and Repair, Society of Cosmetic Chemists and International Society for Bioengineering and the Skin: Joint Educational Symposium: Evaluation of the Skin Barrier: Breakdown and Repair, New York, NY, Wednesday December 6, 2000

Evaluation of Stratum Corneum Function Using the Moisture Accumulation Test, Department of Dermatology, Veteran's Administration Hospital, San Francisco, CA, October 29, 2000.

Stratum Corneum Physiology and Moisturizing Mechanisms, St. Louis Society of Cosmetic Chemists Annual Scientific Seminar, St Louis, MO, September 29, 2000

Hair care product testing, Consumer Products - Business Unusual, Symposium of the Connecticut Chapter of the Society of Cosmetic Chemists, Stamford Connecticut, September 19, 2000.

Evaluation of skin barrier function by measurement of electrical properties under probe occlusion, International Society for Bioengineering and the Skin, Jerusalem, Israel March 26-30, 2000

Skin Care: Meeting of the Western Ohio American Association of Diabetes Educators, Dayton OH, March 9, 2000.

We need better than Neanderthal techniques to study the neonatal barrier, 12th International Contact Dermatitis Symposium, San Francisco CA, October 14-18, 1999.

How do cosmetics moisturize skin?, Society of Cosmetic Chemists, Long Island Chapter, 1998 Educational Seminar, Melville NY, September 9, 1999.

Effects of α -hydroxy acids on human skin, 4th Romanian International Symposium on Cosmetic and Flavor Products, Iasi Romania, June 1-4, 1999

Similarities and Differences in Physical Properties of Gray and Pigmented Hair, Second Intercontinental Meeting of Hair Research Societies, Washington DC, November 5-7, 1998.

Comparing the effects of lactic acid and glycerin on human skin *in vivo*, Society of Cosmetic Chemists Area IV Symposium, Emerging Technologies in Skin Care, Myrtle Beach, SC October 9-10, 1998.

Skin Care Products in the Nursery, National Association of Neonatal Nurses, Annual Meeting, Cincinnati OH, September 25, 1998.

Racial Differences in Skin Barrier Function in Adults and Infants, Society of Cosmetic Chemists, Long Island Chapter, 1998 Educational Seminar, Melville NY, September 10, 1998.

Comparing the effects of lactic acid and glycerin delivered from simple formulations, Society of Cosmetic Chemists (SCC), Area II Technical Symposium, Chicago IL, September 19, 1997.

Using the Cutometer and Dermal Torque Meter for skin elasticity measurements, Ohio Valley Chapter of the SCC, Cincinnati OH, September 17, 1997.

Practical Aspects of Skin Elasticity Measurement, University of Cincinnati, Department of Dermatology Procter and Gamble Lecture, Cincinnati OH, June 19, 1997.

Gray and Pigmented Hair: Are they different, Scientific Seminar on Haircare, California Chapter of the SCC, Los Angeles CA, May 6, 1997.

Differences in mechanical properties and set in gray and pigmented human hair, Mid Atlantic Chapter of the SCC, Baltimore MD March 11, 1997.

AHA Update, California Chapter of the SCC, Los Angeles CA, February 25, 1997

Skin Elasticity Measurements for Cosmetic Science, Lake Erie Chapter of the SCC, Akron OH, February 18, 1997.

Modeling Stratum Corneum Elasticity with the Dermal Torque Meter, 11th Biannual Symposium of the International Society for Bioengineering and the Skin(ISBS), Zurich, Switzerland, October, 3-5, 1996.

Biomechanical Properties of Skin, Dermal Clinical Evaluation(DCES) Society Annual Educational Seminar, Tarrytown, NY, September 20, 1996.

Latest concepts from academia, The living stratum corneum, HBA Global Expo, Symposium on 21st Century Skin Care, New York, NY, June 3, 1996.

Comparison of Cutometer and Dermal Torque Meter for skin elasticity measurements, ISBS, 20th Anniversary Symposium, Miami, FL, February 15-17, 1996.

Mechanical properties and set in gray and pigmented hair, ISBS, 20th Anniversary Symposium, Miami, FL, February 15-17, 1996.

Practical protocols for mildness evaluation using bioinstruments, Joint SCC-ISBS Symposium, Instrumental Testing of Claim Support, New York, NY December 6, 1995

Alpha-hydroxy Acids, Cosmeceuticals?, "New Compounds in Skin Care: The future of topical preparations, Symposium Sponsored by Bausch & Lomb, Amelia Island, Florida, April 8, 1994.

Fruit Acids in Cosmetics, American Academy of Dermatology, Cosmetic Forum, Washington DC, December 8, 1993.

Use of electrical measurements to assess skin barrier function, Cutaneous Biometrics & Bioengineering of Skin, New York, NY, December 8, 1993.

Biophysical assessment of skin condition: A practical overview, DCES Education Seminar IX, Washington DC, September 11, 1992.

Effects of moisturizer treatment on some clinical and biophysical properties of aging skin, Technical Seminar of the Lake Erie and Ohio Valley Chapters of the SCC, Columbus, Ohio October 25, 1991.

Biophysical evaluation of efficacy in skin and hair care products, Fall Symposium of the Golden Gate Chapter of the SCC, San Francisco, CA, October 11, 1991

Biophysical methods as adjuncts to clinical testing of hand and body lotions, SCC-ISBS, Joint Symposium on Biophysical Methods for Product Evaluation, Chicago IL, May 1, 1991.

Product Effects on the Biophysical Properties of Skin, Annual Education Seminar VII of the DCES, Washington DC, September 14, 1990.

The relationship between the effects of chemical and physical properties of hair and the development of permanent set, Midwest Chapter of the SCC, September 1989.

Viscoelastic properties of skin and hair, 7th ISBS Symposium, Milwaukee Wisconsin, June 1988

Stress Decay Studies of Hair Reduction, ISBS Symposium on Biophysical Measurements of Skin, Hair and Nails, Philadelphia, PA, September 1987

Mechanisms of Stratum Corneum Plasticization, Joint ISBS-SCC Symposium in honor of Tom Cook, New York, NY, December 1986.

Physical and Mechanical Testing of Skin, Skin Science Symposium sponsored by the Florida Chapter of the SCC. April 19, 1986.

Kinetic Studies of Hair Reduction using a Single Fiber Method, Ohio Valley Chapter, Society of Cosmetic Chemists, October 1985.

Thermal analysis of human and swine stratum corneum structure: Identification of transitions due to cell envelopes, Sixth Conference on Epidermal Differentiation, St. Claire, Michigan, July, 1977

SHORT COURSES AND WORKSHOPS

Skin Care Science One day class, Ecatarina Merica Lecture Series for the International Federation of Societies of Cosmetic Chemists Bogota Columbia October 26, 2023.

Hair Care Science One Day Class Ecatarina Merica Lecture Series for the International Federation of Societies of Cosmetic Chemists Medellin Columbia October 24, 2023.

Clinical and Instrumental Testing of Skin, One-day course taught for the Lake Erie chapter of the Society of Cosmetic Chemists, October 17, 2022.

Basic and Advanced Skin Science, Two-day course for the Society of Cosmetic Chemists, Asheville NC, August 22-23, 2019

Measuring the Mechanical Properties of Skin, workshop World Congress of the International Society for Biophysics and Imaging of the Skin San Diego, California, May 1, 2018

Clinical and Instrumental Testing of Skin, One-day course, Society of Cosmetic Chemists, New York NY December 7, 2016

Basic and Advanced Skin Science, Two-day course for the US Food and Drug Administration College Park MD, September 7-8, 2016

Basic and Advanced Skin Science, Two-day course for the Society of Cosmetic Chemists, New York NY March 14-15 2016

Advanced Skin Care Science, One day course for the Society of Cosmetic Chemists, New York NY, May 22, 2015

Instrumental testing for Skin Science, Twin Cities Chapter of the Society of Cosmetic Chemists, Minneapolis MN, April 22, 2015

Electrical and Mechanical Testing of Skin, Hands on Workshop, Cosmetics and Toiletries Summit, Philadelphia, PA, June 25-27, 2014

Basic Skin Science, One day course for the Society of Cosmetic Chemists, Philadelphia PA June 24, 2014.

Instrumental Testing of Skin Care Product Effects on Skin, One day course taught for the Society of Cosmetic Chemists, Newark NJ, April 2, 2014

Skin Care Science – Two-day course taught for the International Federation of Societies of Cosmetic Chemists, Moscow Russia, October 7-8, 2013

Skin Care Science – Two-day course Iasi Taught for the Ecaterina Merica Memorial Education Program, Iasi Romania, October 10-11, 2013

Biochemistry of the Skin, One-day course taught prior to the Society of Cosmetic Chemists Annual Scientific Seminar, St. Louis MO, June 5, 2013

Advanced Skin Science: One day course taught for the Ontario Chapter of the Society of Cosmetic Chemists, Toronto Ontario, March 26 2013

Basic and Advanced Skin Science, 2 day course taught for the Society of Cosmetic Chemists, Newark NJ, April 2-3, 2012

Cosmetic Product Evaluation, 5 day course taught for the International MS in Pharmaceutical Technology, Chulalongkorn University, Bangkok Thailand, August 23-September 3, 2010

Topical Delivery, 5 day course taught for the International MS in Pharmaceutical Technology, Chulalongkorn University, Bangkok Thailand, August 16-20, 2010

Advanced Skin Science, 1 day course for the Society of Cosmetic Chemists Newark NJ, March 23, 2009

Skin Biochemistry, 1 day course for the Florida Chapter of the Society of Cosmetic Chemists, Ft. Lauderdale FL, November 6 2008

Clinical and Instrumental Testing of Skin, 1 day course Society of Cosmetic Chemists, New York NY, December 5, 2007

Advanced Skin Science 1 day course Society of Cosmetic Chemists, Salt Lake City UT, November 11 2007

Skin Science 1 day course XVIII COLAMIQ, Guatemala City, Guatemala October 21, 2007

Hair Care Science, 1 day course, International Federation of Societies of Cosmetic Chemists, Amsterdam, Netherlands September 24, 2007

Skin Care Science for the Cosmetic Scientist, 1 day course, Society of Cosmetic Chemists, Newark New Jersey, June 21, 2007

Formulation and Development of Color Cosmetics, Mae Fah Luang University, MS in Program in Cosmetic Technology, Bangkok branch, Bangkok Thailand, June 2-3, 2007

Lectures in Cosmetic Science, Mae Fah Luang University, Chiang Rai Thailand, May 28 – June 1, 2007

Skin Care Science 1 day course Society of Cosmetic Chemists, Newark NJ, June 21 2007

Advanced Skin Care, 1 day course Society of Cosmetic Chemists Boston MA, May 10, 2006

Basic Skin Care for the Cosmetic Scientist, 1 day course Society of Cosmetic Chemists, Las Vegas, NV June 1, 2005

Cosmetic Product Evaluation, Chulalongkorn University, International MS Program in Pharmaceutical Technology, Bangkok Thailand, December 22-31, 2003

Skin Care Science for the Cosmetic Scientists, 1 day course for the Society of Cosmetic Chemists, New York NY, December 10, 2003.

Skin Science, Intensive course at Chulalongkorn University, International MS Program in Pharmaceutical Technology, Bangkok Thailand, August, 20-24, 2001

Skin Care Science: A basic course for the cosmetic scientist, Society of Cosmetic Chemists annual scientific seminar, Toronto, Ontario Canada, May 10, 2000.

Bioengineering Evaluation of Aging Skin, International Symposium on Bioengineering and Claim Support in honor of Ronald Marks, Liege Belgium, September 10-12, 1999 with GL Grove).

Hair Care Science: A basic course for the cosmetic scientist, Society of Cosmetic Chemists, Los Angeles CA, February 26, 1997.

Ins & outs of testing skin care products: Including new methods to monitor skin changes. Workshop presented at New Technologies in Anti-aging Skin Care, September 9,10 - 1996, Woodcliff Lake, NJ.(with G. Grove)

Skin Care Science for the Cosmetic Scientist:(with L Rhein) Educational Workshop, presented to the Society of Cosmetic Chemists(SCC), New York NY, December 11, 1996.

R. R. Wickett, Hair Removal, Breakfast Workshop, American Academy of Dermatology, Breakfast Symposium, Washington DC, December 6, 1993 (with A. Kligman)

Biophysical Measurements on Skin: A hands-on course, Educational workshop for the SCC, Atlantic City NJ, May 20, 1992. (with GL Grove)

Can non-invasive methodology replace animal testing? Workshop presented to 8th International Symposium on Bioengineering and the Skin, Stresa Italy, June 1990. (with D. L. Miller)

Evaluation of Hair and Nails, Workshop Presented to 7th International Symposium on Bioengineering and the Skin, Milwaukee Wisconsin, June 1988 (with A. Finlay).

SELECTED PODIUM AND POSTER PRESENTATIONS:

RR Wickett, D. Adams, S Burkes and MO Visscher Infant Skin Maturation: Color Features and Biomechanical Properties Over the First Years of Life, World Congress of International Society for Biophysics and Imaging of the Skin, Lisbon Portugal May 31-June 3, 2016

RR Wickett, S Burkes and MO Visscher, Biomechanical Properties of Pediatric Skin and Infantile Hemangiomas, World Congress of International Society for Biophysics and Imaging of the Skin, Mystic CT, June 2-4, 2014

RR. Wickett, Gray and Pigmented Hairs from the Same Individuals may Differ in Both Temporary and Permanent Set. Hairs's13 Conference of the German Wool Research Institute, Lubeck Germany September 4-6, 2013

S. Burkes, RR Wickett, D Adams, MO Visscher *Determination of Infantile Hemangioma Progresion Using Non-Invasive Imaging Modalities*. Poster at Society of Cosmetic Chemists Annual Scientific Seminar, St. Louis MO, June 2013 awarded best student poster

K Wei, C Stella, K Wehmeyer, J Christman, R Johnson, R Wimalasena, T Huggins, L Simms RR Wickett Skin Biomarkers as Objective Measures of Stratum Corneum Barrier Function and Health for Formulating Personal Care Compositions Poster 2617 World Congress of Dermatology Seoul Korean May 24-29 2011

RR Wickett, and MO Visscher, *Factors influencing hand skin health in health care workers: Practices, Environment, Genetics and Treatment Response*, Podium Presentation Society of Cosmetic Chemists Annual Meeting, New York NY, December 2011-

RR Wickett, A Evans and J Marsh, *Interaction of Water Hardness Metals with Human Hair*, Poster at Hairs'11, Meeting of the German Wool Research Institute Munich Germany, September 2011

S. Burkes, K. Burns, MO Visscher and RR Wickett, *Early Effects of the Pulsed Dye Laser on Skin Properties of Burn Scars in Pediatric Patients* Podium Presentation by S. Burkes, World Congress of International Society for Biophysics and Imaging of the Skin, in Buenos Aires Argentina September 24-26, 2010., awarded outstanding presentation at the conference

RR Wickett, *Influence of TNF- α Polymorphism -308 on Neurosensory Response and Irritant Dermatitis*, International Federation of Societies of Cosmetic Chemists Meeting Buenos Aires Argentina, September 2010

RR Wickett, J Davis, D. Said and MO Visscher, *Effect of Hand Hygiene Procedures on Skin Cytokines in Health Care Worker*, Podium Presentation Occupational and Environmental Exposure of Skin to Chemicals, Edinburgh Scotland 14-17 June, 2009

AO Evans and RR Wickett, *A multiparametric study of the impact of water hardness on metals on human hair*, Poster Annual Scientific Seminar Society of Cosmetic Chemists Chicago II, June 4-5, 2009

JA Davis, MO Visscher, RR Wickett, *Role of Cytokine Polymorphism in the severity and treatment of hand dermatitis among health care workers*, Poster Annual Scientific Seminar Society of Cosmetic Chemists Chicago II, June 4-5, 2009

COURSES TAUGHT AT THE UNIVERSITY OF CINCINNATI – (ON CAMPUS AND ONLINE)

Advanced Skin Care Science: (with Professors Gerald Kasting and K. P. Ananthapadmanabhan)

Lectures and homework assignments covering, basic skin anatomy, epidermis and dermis, dermatological terminology, basic biophysical methods for evaluation of skin, structure of the stratum corneum (SC) and SC barrier homeostasis, skin penetration, skin immune system, skin color, sunscreens, phototoxicity, skin moisturizers and anti-aging products and surfactant skin interactions. **Credit Level: G Credit Hours: 3**

Advanced Hair Care Science

This course covers the science of hair and hair care products. Topics include hair growth, morphological and macromolecular structure of hair, physical properties of Hair, reducing agents, reactions and kinetics, permanent waving, straightening and depilation, hair coloring and bleaching, shampoos and conditioners, laboratory and consumer testing methods for evaluating hair properties, hair damage and repair, hair fixatives, dandruff. **Credit Level: G Credit Hours: 3**

Clinical and Instrumental Testing of Skin

This course covers principles of skin clinical testing, including human subject protection, study design and testing on special populations such as infants. The principles behind the most commonly used instruments for studying skin in-vivo are covered along with their use in clinical protocols. Methods covered include skin water loss measurements, electrical measurements, mechanical measurements, Laser Doppler blood flow, Ultrasound imaging, surface contour imaging, optical coherence tomography, skin color measurements, confocal microscopy, skin spectroscopy and magnetic resonance imaging. Protocols for testing moisturizers, cleansing products and "anti-aging" are among those covered. **Credit Level: G Credit Hours: 2**