

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Wella Operations US LLC,
Petitioner,

v.

Olaplex, Inc.,
Patent Owner

Case: IPR2026-00010
U.S. Patent No. 12,214,225

DECLARATION OF LISA GALLO

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I, Lisa Gallo, declare as follows:

1. I am over eighteen years of age, and I am competent to testify regarding the matters set forth in this declaration if called upon to do so.

2. I have been retained by counsel for Wella Operations US LLC (“Wella” or “Petitioner”).

3. I have been informed that Wella recently received a letter from Olaplex, Inc. (“Olaplex” or “Patent Owner”), alleging that one Wella’s OPI nail repair products infringes at least claim 1 of U.S. Patent No. 12,214,225 (“the ’225 patent”). I understand that Olaplex purports to be the owner of the ’225 patent.

4. I have been asked to review the ’225 patent (Ex. 1001) and provide certain opinions, including whether claims 1–12 and 15–17 (the “challenged claims”) cover compositions and methods of treatments directed to keratin found in nails, as well as keratin found in hair and skin.

5. I submit this declaration in support of Wella’s Petition for post-grant review of the ’225 patent, although I have not reviewed the Petition itself.

6. In preparation for this declaration, I have reviewed the ’225 patent (Ex. 1001) and its file history (Ex. 1003). I have also considered the other documents or references cited in this declaration.

7. In forming the opinions expressed below, I have also considered relevant legal standards as provided to me by counsel, as well as my own knowledge

and experience. My opinions herein are based upon my personal knowledge, professional judgment, education, and experience gained through my years as a chemist.

8. The '225 patent is directed to “compositions and methods for treating hair and skin, particularly for repairing disulfide bonds in hair or on the skin.” Ex. 1001 ('225 patent) at 1:34–36. I am familiar with the subject matter described in the '225 patent both as of its earliest possible priority date of August 1, 2013, and the filing date of the '225 patent, April 21, 2024. Importantly, my opinions would not change, irrespective of which date is used.

9. I have been asked to consider how a person skilled in the art (“POSA”) would have understood the claims of the '225 patent in light of the disclosure of the '225 patent. Specifically, I’ve been asked to consider Olaplex’s assertion that the challenged claims of the '225 patent cover methods of treating keratin found in hair, skin, *and nails*.

I. QUALIFICATIONS AND BACKGROUND INFORMATION

10. In formulating my opinions, I have relied upon my knowledge, training, and experience. A summary of my qualifications is provided here.

11. I am an expert in cosmetic formulations and product development. I have nearly 30 years of experience in research, development, and manufacture of various cosmetic formulations and products including skincare products, makeup,

hairecare products, as well as nail polish and treatments. Additionally, I have more than ten years of experience in industrial chemistry, wherein seven of those years were spent working with solvent-based coatings and inks.

12. I received a bachelor's degree in chemistry in 1985 from Merrimack College in North Andover, Massachusetts. Immediately after graduating, I began working as a chemist at Onyx Chemical where I synthesized anti-microbials for contact lenses. After Onyx I worked at Graver Chemical, where I performed work on ion exchange resins for industrial filtering such as water and beer liquids. While working for Onyx and later Graver, I was also enrolled in Montclair State University's graduate program in Montclair, New Jersey. I successfully completed my master's degree in chemistry in 1993.

13. In 1987, I was hired as an entry-level chemist in the coatings and inks division at BASF Corporation. While at BASF, I gained experience in color chemistry as well as coating and ink technology, where I formulated solvent-based printing inks which have similar chemistries to nail enamel products.

14. During my seven years at BASF, I was the lead for various special assignments. These assignments were highly integrated into the printing plants as multiple press trials had to be performed to test and evaluate new technology. For example, one such assignment included formulating water-based printing inks which were not commercialized in publication gravure printing.

15. When I left BASF in 1994, I was a senior chemist and had gained a great deal of experience and knowledge about coatings and color technology which sufficiently prepared me for the next stage in my career at Avon Products, Inc.

16. In 1994, I joined Avon's Research and Development division, based in Suffern, NY. I began my tenure at Avon as a development chemist in the color cosmetics group as part of the lip product team. In this position I developed new formulations for lipsticks, lip balms, and various treatment products. Specifically, I focused on developing these new formulations for the global market, as well as creating extensive shade palettes for use with these formulations. Eventually I was promoted to program leader of the lip product team.

17. Several years later, in my role as program leader, I also assumed leadership responsibility for the nail enamel group, while still maintaining my position as lead for the lip product team. I believe my previous coating and ink experience from BASF played a factor in this promotion. At that time, one of the focuses of the nail enamel group was developing extensive shade palettes. Due to the complexity of the nail category, Avon (and by extension, I) contracted third-party nail enamel vendors to develop products more locally. As the program leader, I was responsible for directing these vendors, which were located across the globe.

18. Around 2000, I was promoted to Senior Manager of the complex eye category, in the color cosmetics division. In this role, I led a team of chemists and

technicians to develop liquid and powder formulations and products for application around the eyes, such as mascaras, eyeshadows, eyeliners, etc. This role provided critical managerial experience but also broadened my technical knowledge and experience for the key categories on the color cosmetics team. During this time, I gained substantial knowledge and experience in product safety, manufacturing operations, as well as product research and development, from concept to market.

19. Around 2007, I was promoted into a new role of Director of Global Innovation. Avon considered this an “upstream” position, which encompassed longer-term, technically complex innovations that were not yet on the marketing calendar. My role was to help build a bridge to link these preliminary development projects with product development teams to eventually launch as new products.

20. As Director of Global Innovation, I focused on color cosmetics, skincare, and to a lesser extent, fragrance. This role not only incorporated formulation technologies but also new technology, process development, and package development. These developments were based on consumer insights and were brand new to the market. Therefore, they were considered high-risk developments requiring strong foundational research with the consumer as well as technical research using ingredients that were new to the cosmetic industry.

21. Some notable and successful product developments under my directorship were Mega Effects Mascara[®], Magix Colorless Face Perfector[®], and

Anew[®] skincare. The Anew skincare brand comprised multiple products. One important aspect of the Anew skincare product line was new formulas incorporating active anti-aging technology with high levels of moisturization in unique textures. Avon's Anew skincare brand was a highly innovative, efficacious, and affordable anti-aging skincare brand and winner of an Edison Award.

22. Another successful product line developed under my direction was Avon's Lotus Shield[®] haircare technology. Development of the Lotus Shield technology started around 2008 and was inspired by the natural superhydrophobic properties of the lotus leaf, i.e., the "lotus effect," protecting the hair by repelling water and dirt to remain clean and smooth even in humid environments. Avon's Lotus Shield haircare technology was launched in 2010 and was also an Edison Award winner.

23. As part of my executive leadership at Avon, I was a key member of Avon's Patent Board which met often to review new patent submissions. The Patent Board would determine which inventions warranted patent protection as part of Avon's strategic patent portfolio. The Patent Board's review and decisions were based on commercial viability and strategic intent. The Patent Board also routinely reviewed Avon's entire patent portfolio and would make recommendations on market expansions. As a result, I am generally familiar with requirements surrounding patents and how cosmetic companies decide what to pursue patent

protection for and how to determine when patents should be filed from a business perspective.

24. In 2014, I was promoted to Vice President of Color Cosmetics Product and Process Development as well as Consumer Product Design. In this role I lead the global color cosmetics category and successfully developed and launched many new products.

25. In addition to the technical aspect of my role, I also supervised the consumer product design team, which had previously been a marketing-led team. Incorporating a research and development focus into this group was challenging but ultimately resulted in a research and development team with strong consumer insights which helped drive successful product development.

26. From 2014 until I retired in October of 2022, I continued to take on additional responsibilities. I ended my career at Avon as Vice President of Global Innovation, leading all categories and developing the Global Portfolio of products in color, skincare, personal care, haircare, toiletries, and fragrance, as well as incorporating process development and package development.

27. As VP of Global Innovation, I successfully leveraged technologies across categories where applicable. For example, leveraging anti-aging actives from skincare with the color cosmetics facial foundation category resulted in unique and efficacious benefits for color cosmetics. Additionally, under my leadership, we

leveraged certain powder technologies from the color cosmetics face team into new eye shadow developments. These activities were successful because technologies were applicable across those categories, but that is not always the case. My extensive knowledge and broad experience in product and formulation development for different substrates (hair, skin, and nails) provided the insight and understanding of which categories could not be leveraged or combined, mainly due to significant differences in the formulation requirements. Nail enamel was one such category.

28. One of the most important contributions I made as VP was development of a turnkey team focusing on quick turnaround launches using third-party vendors. Avon launched several nail products using the turnkey team. For Avon, this was a new way to develop products for Avon's Global portfolio and ensured that all launches were relevant and timely. During this time, I was personally involved in all aspects of product development, including idea generation, product design, sourcing raw ingredients, product safety, supplier identification, formulation development, as well as product launch and commercialization.

29. The following product lines became some of Avon's key brands in its global portfolio: Anew skincare included anti-aging moisturizers for multiple age groups; Advanced Techniques haircare, which included shampoo, conditioners, and treatment products for all hair types; and Avon Color which was across all categories including lip, eye, face, and nail as well as a number of fragrance brands.

30. In addition to my role as VP, I also served as Avon's corporate representative in various talcum powder litigations. I continued in this role after my retirement until August 2024.

31. I am an inventor on U.S. Patent Nos. 6,673,863, 7,431,919, 7,682,621, 7,944,122, 8,128,918, and 9,956,432; U.S. Publication Nos. 2006/0159642, 2009/0087397, and 2012/0259252; U.S. Application Nos. 60/875,467, 61/289,194, and 15/951,698; and International Pub. Nos. WO 2003/051115, WO 2005/018599, WO 2006/019604, WO 2006/068718, WO 2008/077002, WO 2011/078905, WO 2012/061025.

32. During this time, I was also a co-author of several *Future of Beauty* reports, including reports for 2018, 2019, 2021, and 2022. These are annual, research-based reports that analyze societal and consumer trends.

33. I am being compensated for my work associated with this case at an hourly rate of \$750 plus reimbursement of reasonable expenses. My compensation is not contingent on my opinions or the outcome of the case, and I have no other interest in this case or the parties thereto.

II. GROUNDS OF UNPATENTABILITY

34. I understand that the Petition for post-grant review of the '225 patent asserts the following grounds of unpatentability:

- Challenged claims 1–12 and 15–17 lack written description;

- Challenged claims 1–12 and 15–17 lack enablement;
- Challenged claims 1–12 and 15–17 are indefinite.

35. I have not been asked to opine on whether claims 13–14 lack written description, whether they lack enablement, or whether they are indefinite.

III. LEGAL STANDARDS

36. Although I am not a lawyer, I have been advised on the relevant legal principles by Petitioner’s counsel and have used them as a basis for my opinions.

A. Claims

37. I understand that a POSA is a person to which the claimed subject matter pertains with the capability of understanding the scientific and engineering principles applicable to the pertinent art.

38. I understand that the following factors may be considered in determining the level of ordinary skill: the type of problems encountered in the art; prior art solutions to those problems; the speed with which innovations are made; the sophistication of the technology; and the educational level of active workers in the field. I also understand that not every factor may be present and that one or more factors may predominate.

39. I have also been informed and understand that terms in the patent claims must be read as they would have been understood by a POSA at the time of the claimed invention.

40. I understand that the claims within a patent set forth what the inventors have presented as their inventions.

41. I also understand that claims can be independent or in dependent form, meaning that they depend from the identified independent claims and add requirements to those claims.

B. Specification

42. I understand that there are other parts of a patent, including the abstract, the figures of a patent, the background of the invention, the summary of the invention, and the detailed description of the invention. I understand that these portions often are collectively referred to as the “specification” of a patent. I understand that technically, the claims are part of the specification, but that referring to the “specification” typically means referring to the written description of the inventions rather than the claims. I also understand that the specification informs the understanding of the claims by, for example, describing the claimed invention and providing preferred examples of the claimed invention.

C. Priority Date

43. I have been informed that the validity of a patent is assessed from the perspective of a POSA as of the earliest filing date, or priority date, of the patent. I understand that this applies to assessing the validity of a patent, including under the principles of written description and enablement.

44. I understand that the earliest possible priority date for the '225 patent is August 1, 2013. I understand that the '225 patent claims this priority date based on the earliest filed U.S. provisional application no. 61/861,281.

D. Prosecution History or File History

45. I understand that the correspondence back and forth between the representative of the applicant, and the U.S. Patent and Trademark Office (USPTO), leading up to the issuance of a patent is called the “file history” or “prosecution history.”

46. It has been explained to me that, in the process of obtaining a claim of a patent, the inventors and the examiner may make statements explaining their understanding of the scope of their claimed invention. It has also been explained to me that for a statement by the inventors to narrow the scope of a claimed invention, the statement must clearly and unambiguously limit the scope of an invention. I understand this is called “prosecution disclaimer” or “prosecution disavowal.”

47. I understand that the claim language, specification, and file history are referred to as “intrinsic evidence” or “the intrinsic record.” This “intrinsic evidence” is contrasted with evidence from beyond the scope of the patent and the file history, which is referred to as “extrinsic evidence.” I understand that extrinsic evidence is less reliable than intrinsic evidence when determining what certain terms in a patent claim mean.

E. Enablement and Written Description Requirements

48. I have been informed and I understand that the United States patent laws include both a written description requirement and an enablement requirement in 35 U.S.C. § 112(a).

1. Written Description

49. Counsel has explained to me that in order to satisfy the written description requirement, an inventor must show they possessed their invention by sufficiently describing it.

50. More specifically, I have been informed that a patent specification must describe the full scope of the claimed invention in sufficient detail that a POSA can reasonably conclude that the inventor had possession of the claimed invention. I understand that a patent need not describe routine or well-known subject matter, but the invention itself should be contained in the patent specification. I also understand that to provide written description for an entire genus, the patent specification must contain sufficient disclosure to convey that the inventors actually invented the entire genus, rather than simply one or two species within the genus.

51. I have been informed by counsel that claims that lack written description in the specification are invalid.

2. Enablement

52. Counsel has informed and I understand that in order to satisfy the enablement requirement, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.

53. I understand that the law sets forth certain factors called the *Wands* factors; the *Wands* factors are factors that are considered when determining whether a disclosure would require undue experimentation. Counsel has provided me with the following list explanations for the *Wands* factors:

- (1) the nature of the invention: the subject matter to which the claimed invention pertains.
- (2) the breadth of the claims: the scope of the claims.
- (3) the relative skill of those in the art: the relative skill of those in the art in relation to the subject matter to which the claimed invention pertains or with which it is most nearly connected. The relative skill determined at the time the application was filed.
- (4) the state of the prior art: what a POSA would have known, at the time the application was filed, about the subject matter to which the claimed invention pertains. In general, the pertinent art should be defined in terms of the problem to be solved rather than in terms of the technology area, industry, trade, etc. for which the invention is used.

- (5) the amount of direction or guidance presented: the amount of direction or guidance provided by the inventor within the specification.
- (6) the presence or absence of working examples: the working examples disclosed in the specification.
- (7) quantity of experimentation necessary: the quantity of experimentation needed to make or use the invention based on the content of the disclosure.
- (8) the predictability or unpredictability of the art: the ability of a POSA to extrapolate the disclosed or known results to the claimed invention.

54. I have been informed by counsel that claims that are not enabled by the specification are invalid.

F. Indefiniteness

55. I have been informed by counsel that the claims of a patent must particularly point out and distinctly claim the subject matter which the inventor regards as the invention.

56. I understand that a claim is indefinite if the claim, interpreted in light of the specification and the prosecution history, fails to inform those skilled in the art about the scope of the invention with reasonable certainty.

57. I have been informed by counsel that claims that are indefinite are invalid.

IV. LEVEL OF ORDINARY SKILL IN THE ART

58. I understand that a POSA is a hypothetical person who is presumed to have knowledge of all of the relevant art at the time of the alleged invention. I am informed that factors that may be considered in determining the level of ordinary skill in the art may include: (1) type of problems encountered in the art; (2) prior art solutions to those problems; (3) how quickly innovations are made; (4) sophistication of the technology; and (5) educational level of active workers in the field. In a given case, not every factor may be present, and one or more factors may predominate. I am further informed that the qualifications of the POSA may be met by an individual or by a team of individuals. I am also informed that a POSA is a person of ordinary creativity, and would have the capability of understanding the scientific principles applicable to the pertinent art.

59. In my opinion, a POSA would have had a bachelor's degree in chemistry and at least four years of experience in cosmetic science including in hair and skin. Alternatively, a POSA may have an advanced degree in chemistry with at least two years of experience in the same field.

60. I consider myself to have more experience than that of a POSA, based on my qualifications and experience described above with respect to the subject matter in the '225 patent as of at least 2013. As a result, I am able to opine from the perspective of a POSA for the purposes of this declaration. Although I have more

experience, I am placing myself in the shoes of people I have worked with and the experiences and educational levels they had as of 2013.

61. Additionally, or alternatively, if two or more years' experience with nail cosmetics is also required, I have that experience as well, but I do not believe it is required or expected for a POSA with regard to the '225 patent.

62. In forming my opinions for this declaration, I have used the perspective of a POSA as defined above. My opinions, however, would not be affected if a POSA is defined as someone who has slightly more or slightly less experience than described above.

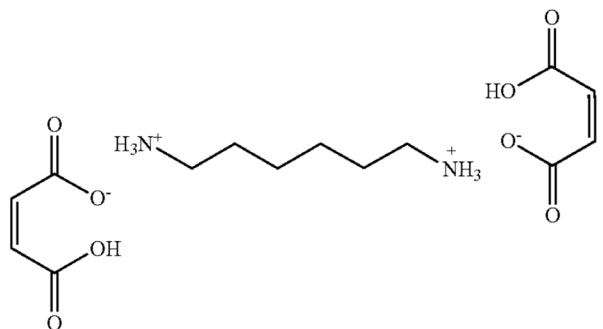
V. THE '225 PATENT

63. The '225 patent, titled *Methods for Fixing Hair and Skin*, issued on February 4, 2025. Ex. 1001 ('225 patent).

A. Claims of the '225 Patent

64. The claims of the '225 patent are as follows:

- Claim 1 – 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:



- Claim 2 – The method of claim 1, wherein the composition further comprises water and an alcohol.
- Claim 3 – The method of claim 2, wherein the composition comprises greater than 1 wt. % water.
- Claim 4 – The method of claim 2, wherein the alcohol comprises ethyl alcohol.
- Claim 5 – The method of claim 1, wherein the composition is in the form of a shampoo.
- Claim 6 – The method of claim 1, wherein the composition is in the form of a conditioner.
- Claim 7 – The method of claim 1, wherein the composition is in the form of a gel.
- Claim 8 – The method of claim 1, wherein the composition is in the form of a cream.
- Claim 9 – The method of claim 1, wherein the composition is in the form of a liquid.
- Claim 10 – The method of claim 1, wherein the composition further comprises a cosmetically acceptable excipient comprising a

surfactant, a vitamin, a preservative, an antioxidant, an emollient, or a pH adjusting agent, or any combination thereof.

- Claim 11 – The method of claim 1, wherein the compound binds to a free thiol in the keratin.
- Claim 12 – The method of claim 1, wherein the compound binds to the keratin through a covalent bond.
- Claim 13 – The method of claim 1, wherein the keratin is comprised in the person's hair and the composition is applied to the person's hair.
- Claim 14 – The method of claim 1, wherein the keratin is comprised in the person's skin and the composition is applied to the person's skin.
- Claim 15 – The method of claim 1, wherein the composition comprises 0.01 wt. % to 25 wt. % of the compound.
- Claim 16 – The method of claim 1, wherein the composition consists of the compound, water, and an alcohol.
- Claim 17 – The method of claim 1, wherein the composition has a pH of 5 to 8.

B. Prosecution History of the '225 Patent

65. The '225 patent was filed on August 21, 2024, as U.S. application no. 18/811,158 (“the '158 application”). Ex. 1001 ('225 patent) at cover.

66. The '158 application is a continuation of a chain of numerous patent applications, going all the way back to the first filed U.S. provisional application no. 61/861,281, filed on August 1, 2013. Ex. 1001 ('225 patent) at 1:6–30.

67. On October 16, 2024, the examiner issued a non-final office action objecting to or rejecting all pending claims. Ex. 1003 ('225 file history) at 179–181. The majority of pending claims were rejected on the ground of nonstatutory double patenting as being unpatentable over claims of related patent family members. Ex. 1003 ('225 file history) at 181–188.

68. In response, the applicant filed a terminal disclaimer identifying the patents referenced in the office action and corrected several minor topographical errors. Ex. 1003 ('225 file history) at 200–204.

69. The examiner issued a notice of allowance on November 12, 2024, noting that compound used in the claimed method was novel and non-obvious over the teachings in the prior art. Ex. 1003 ('225 file history) at 220–221.

C. The Invention Claimed in the '225 Patent

70. As explained above, I was asked to review and assess the '225 patent to determine if the specification supported Olaplex's assertion that challenged claims covered methods of treating keratin found in hair, skin, and nails.

71. Considering this context, I expected the '225 patent to describe these three substrates as well as formulations and methods directed to treating or repairing keratin found in hair, skin, and nails. That is not what I found at all. To my surprise, the '225 patent is completely lacking any formulations or methods of treatments

indicated for nails and in fact, does not even mention the term “nail.” *See generally*, Ex. 1001 (’225 patent).

72. The specification of the ’225 patent only describes methods and compositions for repairing keratin in hair and skin. For example, according to the field of the invention, “[t]he present invention generally relates to compositions and methods for treating hair or skin, particularly for repairing disulfide bonds in hair or on the skin.” Ex. 1001 (’225 patent) at 1:32–36; *see also* Ex. 1001 (’225 patent) at 3:30–33 (“Compositions, kits, and methods for repairing bonds, for example, disulfide bonds, in hair or on the skin that have been damaged are disclosed.”).

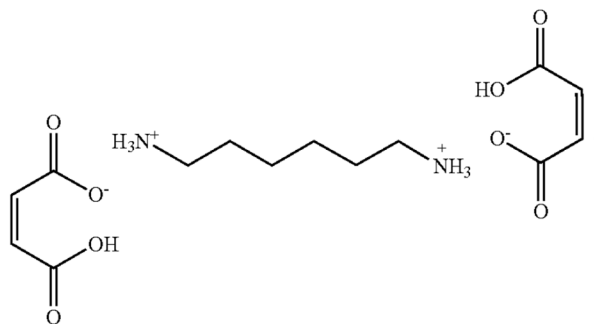
73. More specifically, the ’225 patent explains:

The compositions contain one or more compounds that interact with keratin through more than one binding events (e.g., absorption, binding, etc.) which may involve *reaction with one or more thiols in the hair or on the skin*.

Ex. 1001 (’225 patent) at 3:39–44 (emphasis added).

74. Challenged claim 1, the only independent claim in the ’225 patent identifies the compound or binding agent:

... a composition comprising a compound having a chemical structure of:



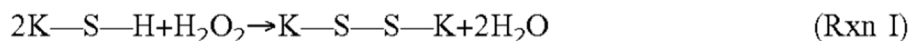
Ex. 1001 ('225 patent) at claim 1.

75. The claimed binding agent is made up of two maleic acid residues, which are described as Michael acceptors, and a hexane diamine linker. Ex. 1001 ('225 patent) at 12:1–6, 16:1–12, 9:8–30, 11:33–12:10.

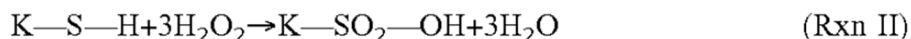
76. The '225 patents states that “formulations [that] contain one or more binding agents” are “concerned with treating hair or skin ... [and] can rebuild latent disulfide bonds in *hair or skin*.” Ex. 1001 ('225 patent) at 7:56–61 (emphasis added).

77. Further, the only reactions illustrating the actions of binding agents, specifically identify the keratin as that which is found in hair:

Treatment with peroxides used in the hair styling process results in the following reaction:

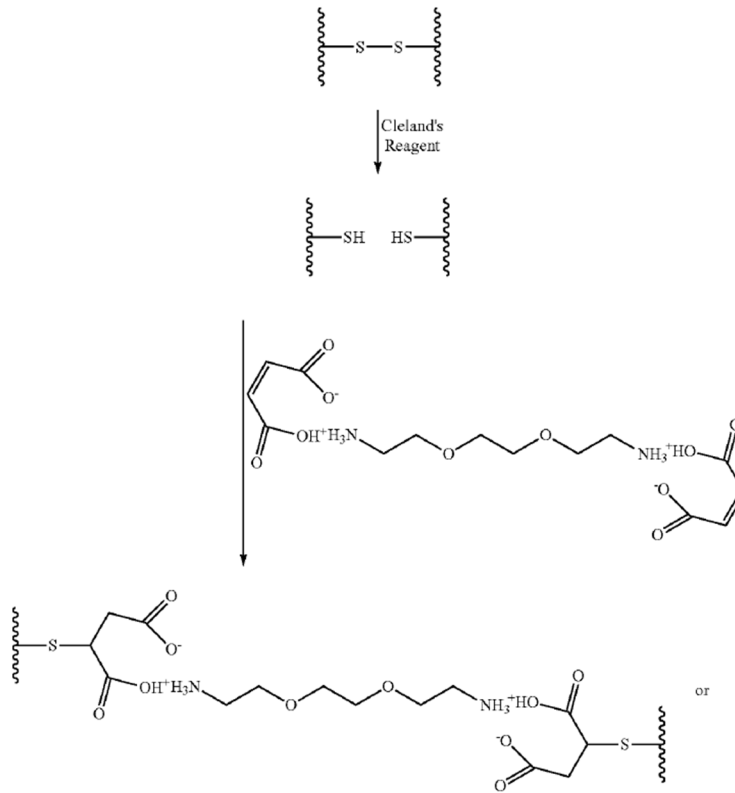


where *K represents keratin in the hair*. However, if two K-S-H groups are not present for the reaction (Rxn I) to take place, it is believed that the following reaction takes place, which *results in damaged hair*.



Ex. 1001 ('225 patent) at 2:17–27 (emphasis added).

The reaction with *thiol groups on hair follicles* is as follows:



Ex. 1001 ('225 patent) at 17:50–19:25 (emphasis added); *see also* Ex. 1001 ('225 patent) at 31:54–55 (“The binding agent covalently binds the free thiols in the hair.”).

78. A POSA would be aware that keratin is found in all types of epithelial cells, including those that line the inside and outside surfaces of the body. Ex. 1004 (NCI definition of keratin). Although the challenged claims¹ do not appear to be

¹ I understand that claims 13 and 14 are not challenged by Petitioner. Claims 13 and 14 each depend from claim 1 and limit the “keratin of a person” in claim 1 to “hair” (claim 13) and “skin” (claim 14). Ex. 1001 ('225 patent) at claims 1, 13, 14.

limited to treating keratin of a particular substrate, for the reasons described above, the specification of the '225 patent is limited to keratin found in hair and skin.

79. Thus, it is my opinion that the methods of treatment disclosed in the '225 patent are directed to treating keratin found in hair and skin, with hair being the preferred substrate.

80. In order to use the claimed binding agent, the '225 patent explains that it is dissolved in a pharmaceutically or cosmetically acceptable composition or carrier, “*suitable for use in contact with the skin, scalp, or hair.*” Ex. 1001 ('225 patent) at 4:33–34, 4:40–44 (emphasis added), 7:63–67. The '225 patent also describes suitable physical forms of the formulations, some of which can be used for hair and skin treatments, while others are substrate specific. Ex. 1001 ('225 patent) *compare and contrast* 20:60–67 with 21:1–8.

81. In addition to repairing keratin in hair and skin (discussed above), the '225 patent further explains that *the compositions also provide* “improved conditioning benefit for dry hair or moisturize the skin.” Ex. 1001 ('225 patent) at 3:32–34. This treatment goal or end result is repeatedly described throughout the patent, including in several of the Examples (with respect to hair):

- There is a need for hair formulations and treatments that can provide *improved conditioning benefit for hair*. Specifically, there is a need to provide *long lasting moisturized feel, smooth feel, and*

manageability control to hair when it is dried. Ex. 1001 ('225 patent) at 3:3–7 (emphasis added).

- There is also a need for skin formulations and treatments that provide improved *conditioning and/or moisturizing benefit to the skin*. In particular, there is a need to provide a *long lasting moisturized and smooth feel to the skin*. Ex. 1001 ('225 patent) at 3:12–15 (emphasis added).
- It is also an object of this invention to provide compositions and methods for *conditioning, moisturizing, and/or otherwise treating the skin*. Ex. 1001 ('225 patent) at 3:24–26 (emphasis added).
- Specifically, the compositions provide *long lasting moisturized feel and smooth feel* without leaving the hair greasy, improved appearance (e.g., sheen), increased dry strength (tensile strength), ease of combing the hair when wet or dried, less hair breakage, and decreased frizz. The compositions also provide a *long lasting moisturized feel and smooth feel to the skin*. Ex. 1001 ('225 patent) at 3:34–40 (emphasis added).
- The hair sample treated with the binding formulation had more shine and felt softer to the touch than the original untreated sample. Ex. 1001 ('225 patent) at 33:66–34:1, 34:44–46 (Examples 4–5).
- A noticeable difference in hair quality between Swatch 1 and Swatch 2 was observed. Swatch 1 hair was softer, less frizzy, appeared hydrated, with more shine than the control, Swatch 2. Ex. 1001 ('225 patent) at 36:25–28 (Example 8).

82. The '225 patent teaches that water would be a pharmaceutically acceptable carrier for the claimed binding agent and further, according to the specification, is the preferred diluent. Ex. 1001 ('225 patent) at 23:31. The '225 patent also explains that other diluents such as ethyl alcohol and isopropyl alcohol may be used for the purpose of enhancing hair or skin penetration. Ex. 1001 ('225 patent) at 23:35–38.

83. A POSA would understand that organic solvents can be used to facilitate penetration, allowing the organic solids to reach the internal region and therefore, the keratin. However, a POSA would know that for hair and skin, the concentration of short-chain alcohols (i.e., ethyl alcohol or isopropyl alcohol) must be low, because they can act as dehydration agents. A POSA would know that when formulations containing high concentrations of a short-chain alcohol are used on particular substrates (i.e., concentrations greater than approximately 0.5–3 wt % for hair and greater than approximately 2–3 wt % for skin), it can dry the substrate, stripping it of the natural oils and causing undesirable and even damaging effects.

84. In contrast, for nails, the formulation comprising the binding agent will require a much higher solvent concentration. A POSA would understand this to some extent. For example, a POSA in 2013 would most likely be aware that compared to the skin and hair formulations described above, nail treatment formulations would contain much higher levels of volatile organic compounds (e.g., short-chain

alcohols). In addition, a POSA would understand (likely from personal experience), that a healthy nail is smooth and hard, not brittle, weak, or peeling. A POSA would understand that any formulation used for treating keratin in nails, should aim to improve the condition of the nail, not produce any undesirable side effects.

85. In hair, formulations containing high levels of volatile organic compounds, such as those used for nail treatments, can lead to dryness, brittleness, and frizz. These formulations can also damage the hair cuticle, the protective outer layer of the hair shaft. This makes the hair more susceptible to breakage and split ends. A POSA would also understand that these formulations could potentially strip color pigments from color-treated hair leading to a dull and faded appearance.

86. In skin, formulations containing high concentrations of short-chain alcohols can cause irritation, including burning, redness, itching, dry skin, inflammation, and even allergic reactions in some individuals.

87. The '225 patent appears to acknowledge these negative effects that short-chain alcohols may have on skin and hair:

The binding agents can be combined with one or more pharmaceutically acceptable carriers and/or excipients that are considered *safe and effective to human hair, skin, and/or human scalp*, and may be administered to an individual's hair *without causing undesirable side effects, such as burning, itching, and/or redness, or similar adverse reactions*.

Ex. 1001 ('225 patent) at 7:63–8:1 (emphasis added).

88. In order to avoid these “undesirable side effects,” the '225 patent describes preferred concentration ranges of specific excipients including water and ethyl alcohol or isopropyl alcohol:

Diluent, as used herein, refers to a substance(s) that dilutes the binding agent. *Water is the preferred diluent.* The formulations typically contains 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. Alcohols, such as ethyl alcohol and isopropyl alcohol, may be used at low concentrations (about 0.5% by weight of the formulation)* to enhance hair or skin penetration and/or reduce odor.

Ex. 1001 ('225 patent) at 23:30–38 (emphasis added).

89. The '225 patent repeatedly describes formulations with high water concentrations as the most preferred. For example, it describes water as a “cosmetically acceptable excipient” that is “typically present in an amount ranging from about 10 wt % to about 99.99 wt % of the formulation, preferably about 40 wt % to about 99 wt %, *more preferably from about 80 wt % to about to about 99 wt %.*” Ex. 1001 ('225 patent) at 19:57–59, 21:9–13 (emphasis added).

90. In fact, every formulation used in the '225 patent Examples, includes only two-to-three components: (1) water; (2) the binding agent bismaleate²; and sometimes, (3) a hair conditioner or highlighting formulation. Notably, the formulations for five out of the eight Examples contain nothing but water and the binding agent, bismaleate. Specifically, the following formulas were tested: Examples 1–3 and 6–7: bismaleate, 3 wt % and water, 97 wt %; Examples 4–5 utilize the same formulation, then further dilute 1:1 with a hair conditioner, cutting the bismaleate solution in half; and Example 8: bismaleate, 24 wt % and water, 76 wt %, then 9 ml of the bismaleate formulation was mixed with 2 oz of a highlighting formulation. Ex. 1001 ('225 patent) at 32:23–26 (example 1), 32:66–67 (example 2), 33:22–24 (example 3), 33:41–44 (example 4), 34:15–18 (example 5), 34:61–64 (example 6), 35:34 (example 7), 35:61–63, 36:1–7 (example 8). Importantly, ***none of the formulations contained any alcohol and only hair keratin was treated.***

91. Aside from the eight Examples and several statements describing water alone or water with a low concentration (0.5 wt %) of a short-chain alcohol, the '225

² Bismaleate or 2,2'(ethane-1,2-diylbis(oxy))bis(ethan-1-amine)di-maleate, appears to utilize a different linker than that recited in claim 1. See Ex. 1001 ('225 patent) at 32:23–24, *compare* claim 1 with 17:25–40, 17:50–19:20.

specification contains no other exemplary formulas or guidance on selecting and preparing formulations comprising one or more binding agents and any of the ingredients found in the exhaustive lists. *See e.g.*, Ex. 1001 ('225 patent) at 22:14–22:16 (surfactants), 22:17–38 (emollients), 22:39–51 (emulsifiers), 22:52–23:11 (preservatives), 23:12–28 (conditioning agents), 23:29–38 (diluent), 23:39–53 (viscosity modifying agents), 23:54–61 (antioxidants), 23:62–67 (opacifying agents), 19:56–23:67 (excipients).

92. Furthermore, according to the '225 patent disclosure, the hair treatments in Examples 1–8 were effective, however, no details were provided regarding the “visual inspections,” and no physical testing was performed. Ex. 1001 ('225 patent) at 32:51–57 (example 1), 33:8–11 (example 2; “visual inspections”), 33:30–33 (example 3), 33:66–34:4 (example 4), 34:44–49 (example 5), 35:15–20 (example 6), 35:51–54 (example 7), 36:25–33 (example 8). Additionally, the '225 patent does not disclose any binding data for any of the binding agents.

93. Thus, for the reasons detailed above, in my opinion, a POSA would conclude that the '225 patent invention is directed to methods of treating keratin found in hair (not nails) using a composition comprising a binding agent and a relatively high water content.

VI. OPINIONS

A. Written Description

94. I have been informed by counsel that the written description requirement exists to show that the inventor actually invented the invention that was claimed.

95. As explained above in Sec. V.C., when I was first provided with the '225 patent and asked to consider Olaplex's assertion that the challenged claims cover methods of treating keratin found in hair, skin, *and nails*, I expected to read about nail treatments (i.e., I expected there to be written description about treating keratin in nails). However, within the first few minutes of my review, I was questioning whether I received the wrong patent. Simply put, the '225 patent is not about nails.

96. While the '225 patent specification mentions the term "hair" 380 times and "skin" 33 times, *it never mentions "nail," "nails," or any other way of referring to human nails or animal nails, claws, talons, hooves, or similar types of tissues. See generally* Ex. 1001 ('225 patent).

97. Also notable, is the fact that "hair" is the only keratin-containing substrate defined in the Definitions section. Ex. 1001 ('225 patent) at 4:23–27.

98. Further, the specification only mentions “keratin” seven times³ and it never identifies keratin as nail keratin:

Substrate	No. of Mentions	Citations
not specified	2	'225 patent at Abstract, 21:43
hair keratin	1	'225 patent at 2:22
skin keratin	3	'225 patent at 2:28–30
hair or skin keratin	1	'225 patent at 3:42–44

99. Additionally, the only reactions illustrating the actions of binding agents, specifically identify the keratin (or the thiol residues that are part of the keratin) as that which is found in hair. Ex. 1001 ('225 patent) at 2:17–27, 17:50–19:25; *see also* Ex. 1001 ('225 patent) at 31:54–55 (“The binding agent covalently binds the free thiols in the hair.”).

100. Similarly, all examples of the treatment method (i.e., Examples 1–8), are hair specific. Ex. 1001 ('225 patent) at 32:11–36:33.

101. Moreover, it is my opinion that a POSA in 2013, reviewing the '225 patent, would take note of the stated treatment goals (i.e., strengthening, improved conditioning, long-lasting moisturized, smooth feel)⁴ and the emphasis on

³ The references cited section and the claims were not included in the word counts.

⁴ *See e.g.*, Ex. 1001 ('225 patent) at 3:34–38.

formulations with high water content and very low or no short-chain alcohols⁵, and would understand that the disclosed formulations and methods would not likely be appropriate or effective as a treatment for nail keratin, which at minimum, would require a formulation with a much higher organic solvent concentration. *See* Sec. V.C. above.

102. For these reasons and the reasons set forth above (Sec. V.C.), the '225 patent is plainly directed to methods of treating keratin found only in human hair and skin.

103. Based on this conclusion, and my understanding of the legal principle of “written description,” it does not appear that there is any written description support for keratin treatment in substrates other than hair or skin.

104. Therefore, it is my opinion that claim 1 of the '225 patent lacks written description for treating keratin found in nails. I understand claim 1 does not recite treating keratin found in nails, however I was asked to consider whether the '225

⁵ *See e.g.*, Ex. 1001 ('225 patent) at 23:30–38, 19:57–59, 21:9–13, 32:23–26, (example 1), 32:66–67 (example 2), 33:22–24 (example 3), 33:41–44 (example 4), 34:15–18 (example 5), 34:61–64 (example 6), 35:34 (example 7), 35:61–63, 36:1–7 (example 8).

patent has any disclosure that suggests the patent applicant had in its possession the invention of using the claimed composition to treat nails, and I see no evidence that suggests the '225 patent contemplates treating nail keratin.

105. Further, the remaining challenged claims 2–12 and 15–17 depend from claim 1 and similarly seek to cover methods of “treating *keratin* of a person” without further limiting the keratin to be treated. Therefore, these claims also lack written description for the same reasons as claim 1.

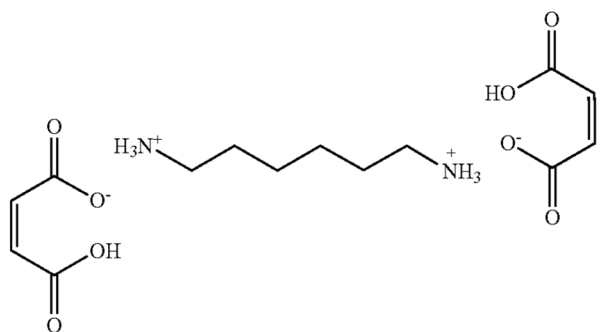
106. It is my understanding that claims that lack written description are invalid.

B. Enablement

107. I have been asked to review and assess whether the challenged claims are enabled under what I understand to be Olaplex’s assertion that the claims cover not only methods of treating keratin found in hair and skin but also cover methods of treating keratin found in *nails*.

108. I understand that in order to satisfy the enablement requirement, the specification must teach a POSA how to make and use the full scope of the claimed invention without undue experimentation.

109. Challenged claim 1 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:”



Ex. 1001 ('225 patent) at claim 1.

110. As explained above (Sec. V.C., VI.A.), the '225 patent specification only describes methods and compositions for repairing keratin in hair and skin. For example, according to the field of the invention, “[t]he present invention generally relates to *compositions and methods for treating hair or skin*, particularly for *repairing disulfide bonds in hair or on the skin*.” Ex. 1001 ('225 patent) at 1:32–36 (emphasis added); *see also* Ex. 1001 ('225 patent) at 3:30–33 (“Compositions, kits, and methods for repairing bonds, for example, disulfide bonds, in hair or on the skin that have been damaged are disclosed.”).

111. Further, the only reactions illustrating the actions of binding agents, specifically identify the keratin (or the thiol residues that are part of the keratin) as that which is found in hair. Ex. 1001 ('225 patent) at 2:17–27, 17:50–19:25; *see also* Ex. 1001 ('225 patent) at 31:54–55 (“The binding agent covalently binds the free thiols in the hair.”).

112. As explained in detail in Sec. V.C, every example in the '225 patent (Examples 1–8), discloses preparing formulations comprising the binding agent of

claim 1 and using those formulations to treat keratin in hair. Ex. 1001 ('225 patent) at 32:11–36:33.

113. Specifically, the specification discloses that the formulations in Examples 1–8 are prepared by dissolving 300 mg or 2,400 mg of a binding agent (bismaleate) in 10 g water (total solution); formulations for Examples 4–5 were further mixed 1:1 with hair conditioner; while in Example 8, 9 ml of the formulation was further mixed with 2 oz of a highlighting formulation. Ex. 1001 ('225 patent) at 32:23–26 (example 1), 32:66–67 (example 2), 33:22–24 (example 3), 33:41–44 (example 4), 34:15–18 (example 5), 34:61–64 (example 6), 35:34 (example 7), 35:61–63, 36:1–7 (example 8). All binding agent formulations as well as controls (formulations without bismaleate) for some Examples, were then used to treat human hair and according to the '225 specification, hair treated with the binding agent was improved over the hair treated with the control formulation or compared to the original hair sample. Ex. 1001 ('225 patent) at 32:51–57 (example 1), 33:8–11 (example 2; “visual inspections”), 33:30–33 (example 3), 33:66–34:4 (example 4), 34:44–49 (example 5), 35:15–20 (example 6), 35:51–54 (example 7), 36:25–33 (example 8).

114. Consistent with the Examples, other sections of the '225 specification explain “[w]ater is the preferred diluent” and is “most preferably greater than 80% (wt).” Ex. 1001 ('225 patent) at 23:30–35, 19:57–59, 21:9–13.

115. The '225 patent also explains that it is beneficial for water-based formulations used for treating hair or skin, to include short-chain alcohols at low concentrations:

Diluent, as used herein, refers to a substance(s) that dilutes the binding agent. Water is the preferred diluent. The formulations typically contains 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*. Alcohols, such as *ethyl alcohol and isopropyl alcohol, may be used at low concentrations (about 0.5% by weight of the formulation) to enhance hair or skin penetration and/or reduce odor*.

Ex. 1001 ('225 patent) at 23:30–38 (emphasis added).

116. In addition to repairing keratin in hair and skin, the '225 patent also explains that *the compositions also provide “improved conditioning benefit for dry hair or moisturize the skin.”* Ex. 1001 ('225 patent) at 3:32–34 (emphasis added). This treatment goal or end result is repeatedly described throughout the specification. Ex. 1001 ('225 patent) at 3:5–6 (“provide long lasting moisturized feel, smooth feel, and manageability control to hair”), 3:12–15, 3:25–26 (“conditioning, moisturizing, and/or otherwise treating the skin”), 3:34–36 (“provide long lasting moisturized feel and smooth feel without leaving the hair greasy”), 3:39–40 (“provide a long lasting moisturized feel and smooth feel to the skin”).

117. As explained above (Sec. V.C.), a POSA would understand that in contrast to the water-based, moisturizing, and conditioning formulations set forth in the '225 patent for use in treating hair or skin keratin, formulations for use in treating nail keratin would likely contain much higher levels of volatile organic compounds (e.g., short-chain alcohols). Notably, none of the exemplary formulations in the '225 patent fit this description. This is not surprising, because this type of formulation would likely be undesirable or even harmful if used on hair or skin.

118. The '225 patent makes clear that the formulations should be prepared in a way to reduce any undesirable side effects to hair or skin:

The binding agents can be combined with one or more pharmaceutically acceptable carriers and/or excipients that are considered *safe and effective to human hair, skin, and/or human scalp*, and may be administered to an individual's hair *without causing undesirable side effects, such as burning, itching, and/or redness, or similar adverse reactions*.

Ex. 1001 ('225 patent) at 7:63–8:1 (emphasis added).

119. Thus, for the reasons described above, it is my 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 the keratin of a person's hair (and potentially skin). It is clear that the '225 patent *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*.

120. Additionally, I have been asked to consider the individual *Wands* factors.

1. The Breadth of the Claims

121. A POSA, reviewing the '225 patent (without the knowledge of Olaplex's broad reading of the claims), would understand that the invention disclosed in '225 patent is solely directed to formulations and methods for treating keratin found in hair.

122. However, based on the plain reading of claim 1, as well as Olaplex's allegations, the method is not limited to treating keratin found only in hair. Accordingly, claim 1 is directed to treating *all keratin* in a person, which is overly broad and unsupported by the specification of the '225 patent.

123. Similarly, the remaining challenged claims 2–12 and 15–17, depend from claim 1 and are similarly directed to treating *all keratin* in a person without further limiting the keratin to be treated. Therefore, these claims are also overly broad and are not enabled.

124. In contrast, non-challenged dependent claims 13 and 14 each limit the “keratin of a person” in claim 1 to keratin found in “hair” (claim 13) and “skin”

(claim 14), and therefore, are not overly broad with respect to the keratin treatment. Ex. 1001 ('225 patent) at claims 1, 13, 14.

125. In my opinion, under Olaplex's reading of the challenged claims to cover treatment of keratin in nails, the breath of the challenged claims is much broader than the '225 patent disclosure and would encompass subject matter that is far beyond what a reader—either myself as a person of extra-ordinary skill in this art, or a person of ordinary skill in this art—would understand to be the subject matter of the described invention. This overly broad reading of the challenged claims also impacts the remaining *Wands* factors as described below.

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

126. I understand that “the relative skill” and “the state of the prior art” are determined at the time the earliest application was filed (August 1, 2013). I also understand from counsel that “the relative skill of those in the art” is considered in relation to the subject matter to which the claimed invention pertains or with which it is most nearly connected. Additionally, I understand that “the state of the prior art” is about the subject matter to which the claimed invention pertains, and in general, relevant art should be defined in terms of the problem to be solved rather than in terms of the technology area, industry, trade, etc. for which the invention is used.

127. As explained above (Sec. IV.), a POSA would have a bachelor's degree in chemistry and at least four years of experience in cosmetic science including in

hair and skin. Alternatively, a POSA may have an advanced degree in chemistry with at least two years of experience in the same field. Similarly, the state of the prior art would be prior art relevant to cosmetic formulations for hair and skin as of August 1, 2013, and would also include art pertaining to methods of treating keratin in hair and skin.

128. In my experience most cosmetic product development companies have distinct groups or divisions that work on formulations for nails or formulations for all other cosmetically relevant substrates. Accordingly, it has also been my experience that the majority of chemists that begin their career working in nail formulation development stay in nails or expand into other color cosmetic teams. Similarly, in my experience, chemists that begin their career working in hair and/or skin formulation development stay in hair and/or skin.

129. Relying on my 40 years of experience and having been one of the rare individuals with experience in both categories, my opinion is that a POSA in hair cosmetic chemistry, would not be a POSA of nail cosmetic chemistry.

130. As described elsewhere in this declaration, this relative skill level, i.e., one having experience with hair and skin, would not find the disclosure of the '225 patent to enable a composition for treatment of nails. Even if the level of skill were higher, either additional schooling and/or additional work experience, such a reader

would still not find the disclosure of the '225 patent to enable a composition for treatment of nails.

3. Amount of Direction or Guidance Presented and the Absence of Working Examples

131. As explained above, there is *no disclosure* in the '225 patent of any formulations or methods directed to *treating keratin found in nails*. The only exemplary formulations for treating keratin are the four, hair treatment formulations disclosed in Examples 1–8. *See* Ex. 1001 ('225 patent) at 32:11–36:33; *see also* Sec. V.C., VI.B. Similarly, *all working examples* of the treatment method (i.e., Examples 1–8), *are hair specific*. Ex. 1001 ('225 patent) at 32:11–36:33; *see also* Sec. V.C., VI.B.

132. Importantly, and as explained in the preceding section, a POSA with a chemistry degree and experience in hair and skin cosmetic formulations as of August 2013, would understand that just because a formulation is effective at treating keratin in hair, does not necessarily mean that the same formulation would be effective at treating keratin in other substrates, especially nails.

133. At a minimum, a POSA would understand that generally, formulations for use in hair are very different than those for use in nails. For example, a POSA would be well aware that when you dye hair, the dye goes inside the hair, but in order to dye/color nails, the color stays on top. A POSA would understand that the

reason for these vastly different techniques and formulations is due to the different substrates.

134. For this reason, a POSA would need a great deal of direction or guidance in order to make a formula for treating nails, then use that formula in a method to successfully repair the nail keratin. The '225 patent provides no guidance or direction for selecting or formulating a composition to use to treat nail keratin. Additionally, the '225 patent does not provide any direction or guidance with respect to the treatment method itself (i.e., application of the treatment formulation to the nail).

135. As described above (Sec. V.C.), the only guidance or direction in the '225 patent, for preparing and using a composition or formulation, is the eight working examples and several statements within the specification that describe the *preferred* use of water alone or water with a low concentration (0.5 wt %) of a short-chain alcohol. Ex. 1001 ('225 patent) at 32:23–26 (example 1), 32:66–67 (example 2), 33:22–24 (example 3), 33:41–44 (example 4), 34:15–18 (example 5), 34:61–64 (example 6), 35:34 (example 7), 35:61–63, 36:1–7 (example 8), 7:63–8:1, 24:5–6.

136. The '225 specification contains no other exemplary formulas or guidance on selecting and preparing formulations comprising one or more binding agents and any of the ingredients found in the exhaustive lists. *See e.g.*, Ex. 1001 ('225 patent) at 22:14–22:16 (surfactants), 22:17–38 (emollients), 22:39–51

(emulsifiers), 22:52–23:11 (preservatives), 23:12–28 (conditioning agents), 23:29–38 (diluent), 23:39–53 (viscosity modifying agents), 23:54–61 (antioxidants), 23:62–67 (opacifying agents), 19:56–23:67 (excipients).

137. In my opinion, a POSA would understand that a formulation effective at treating keratin in hair would not be useful or effective at treating keratin in nails and thus, the POSA would be essentially starting from scratch, with no guidance or any working examples. As described below, the nature of the invention and the unpredictability of the art would only add to the quantity of experimentation necessary for a POSA to arrive at a formulation and treatment method that would be effective at repairing the keratin in nails and achieving the desired end result of smooth, hard, flexible nails.

4. Nature of the Invention and Unpredictability of the Art

138. I have been informed that the nature of the invention factor is defined as the subject matter to which the claimed invention pertains.

139. In my opinion the subject matter of the '225 invention is in part within the field of biology, specifically in vivo biology, as well as in the field of chemistry.

140. Inventions within the fields of chemistry and biology, especially in vivo biology, are more unpredictable and may require a POSA to have more relative skill in the art and/or require more guidance and more working examples in the patent disclosure.

141. However, as explained above, Olaplex's overly broad reading of the challenged claims to include treatments of keratin found in nails, is unsupported by the disclosure. As mentioned above (Sec. VI.B.3), this lack of guidance as well as the lack of any relevant working examples forces a POSA to essentially start from scratch to formulate a suitable composition and develop an effective method for treating nail keratin.

142. In my opinion, a POSA with experience in hair and skin substrates in August 2013, would find the task of developing a suitable formulation and method to treat nail keratin very unpredictable. Particularly, due to the lack of guidance and absence of working examples directed to nails, in the specification of the '225 patent, but also due to the nature of the invention and the relative skill of those in the art.

143. For example, a POSA would have to consider many variables when attempting to determine the ingredients of the formulation, such as the type and concentration of the solvent, the percentage of water, any other excipients such as those listed in the '225 patent as well as their concentration. *See e.g.*, Ex. 1001 ('225 patent) at 22:14–22:16 (surfactants), 22:17–38 (emollients), 22:39–51 (emulsifiers), 22:52–23:11 (preservatives), 23:12–28 (conditioning agents), 23:29–38 (diluent), 23:39–53 (viscosity modifying agents), 23:54–61 (antioxidants), 23:62–67 (opacifying agents), 19:56–23:67 (excipients).

144. Further, in my opinion, a POSA would find it difficult and unpredictable, to select and prepare a formulation that would deliver the binding agent to the nail keratin most effectively. Additionally, a POSA would find it very difficult to predict the concentration of binding agent needed to provide effective crosslinking of the nail keratin for the particular method of treatment and ultimately strengthening the nail.

145. Moreover, POSA with experience in hair and skin substrates, would find the task of developing a formulation that will lay down on the nail evenly as well as adhere to the nail, somewhat challenging, in particular when compared to laying down a formulation on hair. This step of applying the formulation evenly insuring a smooth even film that adheres and remains in place, is critical to distributing the binding agent to the entire nail bed.

146. Furthermore, while the majority of experiments evaluating hair keratin treatments can be performed on hair samples, studies on nails require human participants. in vivo studies are more costly and more time consuming and also add an additional level of unpredictability due to the inherent variables that cannot be controlled when using human subjects. Notably, no such human experiments are described in the '225 patent specification.

5. The Quantity of Experimentation Necessary

147. As previously explained, the properties of keratin found in hair, skin, and nails is not the same. Thus, the method of treatment is different. For a method of treating keratin to be successful, the formulation needs to be appropriate for the binding agent as well as optimized for the specific substrate. Specifically, when developing the formulation, a POSA would need to ensure the following with respect to the formulation:

- 1) it can be evenly applied to the substrate by hand or an applicator;
- 2) remains in place for a desired period of time;
- 3) ensure access to the keratin within the substrate;
- 4) carry or deliver the binding agent to keratin;
- 5) ensure that upon contact with the keratin, the binding agent is capable of binding to the thiol residues and cross-linking the keratin;
- 6) ensure that enough binding agent reaches the keratin to effectuate repair;
- 7) formulation alone should enhance the benefits of the binding agent; and
- 8) yield a measurable improvement to the overall condition of the substrate.

148. The '225 patent describes a method of treatment that repairs the disulfide bonds of keratin in the hair, while achieving an end result of soft, smooth, moisturized hair. Ex. 1001 ('225 patent) at 3:30–40.

149. As explained above (Sec. VI.B.3.), because there is no guidance in the '225 specification for nail treatment formulations and no working examples, a POSA

would need to essentially start from scratch in order to develop a suitable formulation and method effective at treating nail keratin using the binding agent of claim 1. For the reasons described below, the quantity of experimentation necessary would be great.

150. A POSA would have a general understanding that treating keratin in nails is not the same as treating hair keratin. As explained above in Sec. VI.B.2., a POSA would have experience with hair or skin cosmetic formulations but would most likely not have any experience with nail formulations. Thus, this individual would probably be aware that the exemplary or preferred '225 patent formulations would not work as nail treatments, but it is also possible that they would be unsure.

151. If a POSA was unsure, I believe that their initial experiments would begin with the exemplary hair treatment formulations disclosed in the '225 patent, which would ultimately be ineffective at crosslinking the nail keratin and would also not achieve the desired end result or condition of the nail. The consequence of the relative skill in the art (lack of experience in nail cosmetics) would simply add additional time and resources to the quantity of experiment necessary.

152. As is clear from just a high-level description of necessary experiments, the quantity of experimentation required to make and use a composition comprising the claimed binding agent to treat keratin in nails based on the content of the '225 patent disclosure is significant. More importantly, there is no guidance in the

specification about how to structure these experiments or what to look for in a nail-focused experiment. *See* Sec. VI.B.3. It is this complete lack of disclosure that makes this analysis complicated and injects significant amounts of guess work. *See* Sec. VI.B.4.

153. While it is conceivable that I may be able to devise an experiment, such an experiment comes from the years of experience unique to my education and work history. Nothing in the specification suggests a POSA would have conceived of or contemplated constructing such an experiment to develop a formulation based on the '225 patent's disclosure limited to treating keratin while also moisturizing hair and potentially skin.

154. This is due to the overly broad challenged claims that do not appear to limit the method of treating keratin in a person to only hair and skin but also encompass nail keratin. *See* Sec. VI.B.1. Additionally, the lack of guidance and working examples directed to methods and formulations for treating nail keratin adds to the unpredictability and may require more skill or experience than is already required for treating hair keratin. *See* Sec. VI.B.2–4. Furthermore, the state of the prior art will not affect the unpredictability or the decrease the quantity of experimentation in a meaningful way because any new formulation that is developed for use in nails will include the binding agent of claim 1. *See* Sec. VI.B.2. The prior art available as of August 1, 2013, would not provide the teachings necessary to

select an appropriate formulation that will deliver the binding agent to the nail and allow it to effectuate the cross-linking of the nail keratin. *See* Sec. VI.B.2.

155. Therefore, for the reasons stated above, it is my opinion that the challenged claims of the '225 patent lack an enabling disclosure for treating keratin found in nails.

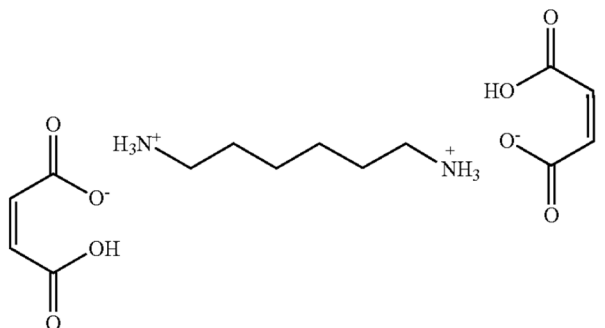
156. Further, because challenged claims 2–12 and 15–17 depend from claim 1, and do not further limit the keratin to be treated, these claims lack enablement for the same reasons as claim 1.

157. It is my understanding that claims that are not enabled are invalid.

C. Indefiniteness

158. I have been informed by counsel that claims are indefinite if they fail to inform a POSA with reasonable certainty about the scope of the invention.

159. Challenged claim 1 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:”



Ex. 1001 ('225 patent) at claim 1.

160. In my opinion, a POSA reading the challenged claim 1, would be uncertain as to what exactly “*keratin of a person*” means with respect to the claimed method of treatment.

161. As explained above (Sec. V.C.), a POSA would be aware that keratin is found in all types of epithelial cells, including those that line the inside and outside surfaces of the body. Ex. 1004 (NCI definition of keratin). With this knowledge, and with no additional context or limitations in at least challenged claim 1, a POSA would either believe that the method may somehow be applicable to all types of human keratin or more likely, would just have to take a guess at which keratin-containing substrate they believe the claimed invention is directed to.

162. There is nothing in the challenged claim that informs a POSA which type of keratin will be treated.

163. Additionally, it is my opinion that “*treating*” is also uncertain in challenged claim 1.

164. As explained in Sec. V.C, a POSA would understand that the method of treating keratin requires compositions that must be suitable for use in the particular target substrate. In addition, a POSA would understand that the same composition will need to be an acceptable carrier for the claimed binding agent in order for it to be effective.

165. For example, the '225 patent informs that preferred formulations used in treating keratin found in hair are water-based with a low concentration (about 0.5 wt %) of short-chain alcohols. Ex. 1001 ('225 patent) at 23:30–38. In contrast, for nails, a POSA would likely understand that the formulation would require a much higher solvent concentration. *See* Sec. V.C.

166. Furthermore, a POSA would recognize that a method of treatment that attempted to use the hair treatment formula on nails would not likely be effective, and alternatively, if the nail treatment formulation were used on hair, it would likely lead to undesirable effects or even damage the hair. Ex. 1001 ('225 patent) at 7:63–8:1; *see also* Sec. V.C.

167. In addition, as described above, there are additional end results of treatment that are substrate-specific, such as improved conditioning or moisturizing for treatment of skin or hair, as opposed to improved smoothness and hardness for nails. Ex. 1001 ('225 patent) at 3:32–34; *see also* Sec. V.C.

168. There 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.

169. Therefore, it is my opinion that challenged claim 1 does not inform a POSA with reasonable certainty about the scope of the invention, thus it is indefinite.

170. Similarly, the remaining challenged claims 2–12 and 15–17 depend from claim 1 and similarly seek to cover methods of “*treating keratin* of a person” without further limiting the keratin to be treated. Therefore, these claims are also indefinite for the same reasons as claim 1.

171. It is my understanding that claims that are indefinite are invalid.

VII. RESERVATION OF RIGHTS

172. I reserve the right to amend or supplement this declaration as this case proceeds and any additional information comes to light.

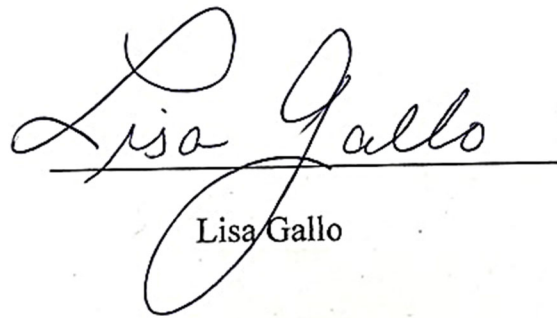
173. I understand that traditionally no live expert testimony is used at the PTAB, and I presently have no plans to testify, however should I be asked, I reserve my right to use exhibits to summarize or exemplify my opinions (including exhibits I have not yet created) if called to testify.

174. If it would be helpful to the PTAB, I am willing and able to provide additional background.

175. I further reserve the right to respond to any opinions presented by any of Patent Owner’s experts regarding the meaning of any claim term or limitation within the challenged claims. I also reserve the right to provide further opinions in this case, such as opinions regarding non-infringement and/or invalidity of the ’225 patent, if requested to do so.

176. I declare under penalty of perjury that this declaration contains a true and correct statement of my opinions, based on the information available to me.

Dated: November 3, 2025



Lisa Gallo