

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Wella Operations US LLC
Petitioner

v.

Olaplex, Inc.
Patent Owner

Case PGR2026-00010
Patent No. 12,214,225 B2

PETITION FOR POST GRANT REVIEW

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1001	U.S. Patent No. 12,214,225 to Pressly et al., issued February 4, 2025 (“’225 patent”)
1002	Declaration of Lisa Gallo
1003	File History of U.S. Patent No. 12,214,225
1004	NCI Dictionary of Cancer Terms, National Cancer Institute, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/keratin (accessed October 23, 2025)
1005	File History of U.S. Patent Application No. 15/290,593
1006	U.S. Patent No. 9,668,954
1007	U.S. Patent No. 9,326,926
1008	U.S. Patent No. 9,498,419
1009	U.S. Patent No. 9,095,518
1010	U.S. Patent No. 9,144,537
1011	U.S. Patent No. 9,855,447
1012	U.S. Patent No. 10,639,505
1013	U.S. Patent No. 11,446,525
1014	U.S. Patent No. 12,233,289
1015	Letter from Olaplex
1016	U.S. Patent No. 11,628,148
1017	As-filed specification from 14/257,056

I. PRELIMINARY STATEMENT

Wella Operations US LLC (“Petitioner”) received a letter from Olaplex, Inc. (“Patent Owner”) alleging infringement of U.S. Patent No. 12,214,225 (“’225 patent”) by one of Petitioner’s nail treatment products. Ex. 1015. A basic review of the ’225 patent, however, demonstrates it is directed to methods of treating keratin found in hair or skin, not keratin found in nails. Given that Patent Owner appears to be taking an overly broad reading of the scope of the ’225 patent to allege infringement by nail treatment products, among other issues with claims 1-12 and 15-17 (the “Challenged Claims”), Petitioner seeks Post-Grant Review of the ’225 patent for a finding that the Challenged Claims lack enablement, lack written description, and are indefinite.

The ’225 patent broadly claims a method for treating keratin in a person (i.e., *all keratin* in a person). Ex. 1001, cl 1. However, the ’225 patent only discloses treatment of two types of keratin-containing substrates: skin and hair. *Id.*, 3:41-44 (“The compositions contain one or more compounds that interact with keratin ... in the hair or on the skin.”), 7:56-57 (“The formulations disclosed herein are concerned with treating hair or skin.”), 1:34-36.

The purpose of the ’225 patent is to provide methods of treating keratin in hair and skin. *Id.*, 3:30-31. The objects of the patent specifically include providing compositions and methods of use for repairing ruptured disulfide bonds in keratin of

skin and hair, as well as strengthening and conditioning hair and moisturizing and conditioning skin. *Id.*, 3:3-26, 3:30-44. To this end, the patent details eight examples for treating hair. *Id.*, 32:11-36:33. This focus on keratin in hair, to the exclusion of all other keratin, is all confirmed by and consistent with the Field of the Invention: “The present invention generally relates to compositions and methods for treating hair or skin, particularly for repairing disulfide bonds in hair or on the skin.” *Id.*, 1:34-36.

The claims of the '225 patent breach the bargain between the public and patent owner by attempting to expand the scope of claim coverage beyond that which was originally disclosed. Specifically, the claims of the '225 patent, while directed to a genus, e.g., methods of treating *all* human keratin present in or on a person's body, are attached to a specification that at best only describes or enable a specific species, e.g., methods of treating keratin found in *hair* or *skin*, not *all keratin* that exists in a person. The '225 patent specification provides eight working examples for treating hair keratin, but discloses no examples or embodiments that treat or repair any other keratin-containing substrates. Ex. 1001, 32:11-36:33. Such a blatantly deficient disclosure simply does not support the broad claim scope the Patent Owner attempts to allege, under either the enablement or written description requirements of 35 U.S.C. § 112.

By broadly claiming a genus when the '225 patent specification only discloses

two species among the many species of the genus, Patent Owner is effectively attempting to gain patent protection for claims that are far too broad, as evidenced by the fact that Patent Owner first attempted to prosecute such claim scope in a separate, and later-filed patent family. Patent Owner sought patent protection for this broader concept previously, via a patent application directed towards methods of treating hair, skin, *and nails*. But Patent owner subsequently abandoned the application in favor of claim scope limited to methods of treating hair.

With the '225 patent's broad claims covering methods of treating not just keratin in hair or on skin but *all keratin*, Patent Owner is getting more than they gave in examination and disclosure, and is removing from the public sphere subject matter Patent Owner did not invent.

Petitioner respectfully submits that this PGR should be instituted and all challenged claims held unpatentable.

II. THE '225 PATENT

A. Specification

The '225 patent describes “formulations ... concerned with treating hair or skin.” *Id.*, 7:56-57. The “formulation for treating hair may be in any suitable physical form ... [including,] lotions, milks, mousses, sprays, gels, creams, shampoos, conditioners, and the like.” *Id.*, 20:60-63; *see also id.*, 21:1-4 (formulation forms suitable for skin). The formulations for treating keratin in hair or skin comprise one

or more binding agents as well as any of the following excipients: surfactants, emollients, emulsifiers, preservatives, conditioning agents, diluents, viscosity modifying agents, antioxidants, or opacifying agents. *Id.*, 7:61, 19:56-23:67. The field of the invention states that the “present invention generally relates to compositions and methods for treating hair or skin.” *Id.*, 1:32-35.

The '225 patent further describes methods and “[k]its for treating hair” “that repair and/or strengthen damaged hair and rebuild stronger bonds in hair[.]” *Id.*, 26:13-32:9, 3:9-11. The '225 specification outlines eight different examples of making and using the proposed binding agent formulations; each of the eight examples discloses using and testing the formulation on hair samples. *Id.*, 32:11-36:33.

The specification describes the preferred use of water-based formulations and optionally including short-chain alcohols at very 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.

Id., 23:29-38. Despite this proposed narrow application, claim 1 doesn't even require

alcohol or water, and claims 2 and 3 are directed to compositions for treating keratin in a person, so long as the treatment's composition has any amount of alcohol or water (claim 2) or at least 1 wt% water (claim 3). *Id.*, 36:64-37:2; *see also id.*, 19:57-59, 20:56-59.

This means a formulation with a very high alcohol content and a very low water content would in theory be covered by claims 2 and 3, however, such a formulation would cause an inapposite result of the objective of the '225 patent. This is because certain alcohols, called short-chain alcohols (e.g., ethyl alcohol or isopropyl alcohol), are dehydration agents, and it follows that with increased content of short-chain alcohol, a formulation will have a greater drying effect on the substrate. Ex. 1002, ¶83. Thus, a formulation with a high short-chain alcohol content (i.e., 50%, 75%, or 99%) would fail to moisturize or condition skin and hair, and instead would cause undesirable effects such as burning, itching, redness, or other adverse side effects. *Id.*, ¶¶85-86.

Following a detailed description disclosing only references to the use of the proposed inventive formulations on skin and hair, claim 1 of the '225 patent recites broadly “[a] method of treating keratin of a person,” unbound by application environment. Ex. 1001, 36:47.

B. Prosecution History

The '225 patent, filed August 21, 2024 as application number 18/811,158

(“the ’158 application”), is a continuation of application 18/177,011, filed March 1, 2023, which is itself a continuation of a continuation of a continuation, dating back to PCT Application PCT/US2014/049388 (“the ’388 PCT”). Ex. 1003, 1; Ex. 1002, ¶¶65-66. The ’388 PCT, filed August 1, 2014, claims priority to provisional applications 62/000,340, 61/861,281, 61/885,898, 61/867,872, and 61/903,239 and is itself a continuation in-part of applications 14/257,056, 14/257,089, and 14/257,076. Ex. 1003, 1.

The ’158 application received a first and only non-final office action in October 2024, rejecting nearly all claims on the grounds of indefiniteness (claim 16) and non-statutory double patenting over claims 1-12 of U.S. Patent No. 9,144,537, claims 1-8 of U.S. Patent No. 9,717,668, claims 1-11 and 17-19 of U.S. Patent No. 9,855,447, and claims 1, 5-10 and 20 of U.S. Patent No. 11,446,525. *Id.*, 180-88; Ex. 1002, ¶67. Patent Owner subsequently filed a terminal disclaimer with the USPTO disclaiming the terminal part of the statutory terms of U.S. Patents 9,095,518, 9,144,537, 9,717,668, 9,855,447, and 11,446,525 to overcome the examiner’s double patenting rejections. Ex. 1003, 204; Ex. 1002, ¶68. The examiner issued a Notice of Allowance on November 12, 2024, and the application published on December 12, 2024. Ex. 1003, 215; Ex. 1002, ¶69. The ’185 application issued as the ’225 patent on February 4, 2025. Ex. 1003, 231; Ex. 1002, ¶63.

1. Olaplex's other attempts to prosecute patents that encompassed nail keratin

In 2016, the same inventors and assignees as the '225 patent also filed U.S. Patent Application No. 15/290,593 ("593 application") directed to Keratin Treatment Formulations and Methods. Ex. 1005, 1. In the '593 application, the inventors demonstrated their comprehension of how to describe compounds for nail treatment: describing formulations "for rebuilding the disulfide bonds in keratin found in hair, skin *or nails*." *Id.*, 54 (emphasis added). However, even in the '593 application, with additional disclosure regarding nails, the USPTO took umbrage with the very issues presented in this Petition.

In response to a restriction requirement, the applicant amended the initial claims to include a new claim 30, which recited:

30. (New) A method for treating nails comprising:

- (a) applying a nail formulation to a nail, wherein the nail formulation comprises an active agent,
wherein the active agent is maleic acid or a salt thereof.

Id., 171. The USPTO responded to the addition of this new claim with rejections under 35 U.S.C. §§ 102 and 103. *Id.*, 206-09. In response, the applicant then amended claim 30 to recite:

30. (Currently Amended) A method for treating nails comprising:

- (a) applying a nail formulation to a nail, wherein the nail formulation comprises an active agent for treating keratin.

wherein the active agent is maleic acid or a salt thereof; and
wherein the nail formulation does not contain any additional
active agent for treating keratin.

Id., 253 (emphasis in original). Subsequently, the USPTO issued a final rejection in which it rejected claims 30-46 as lacking written description and claims 30-44 as indefinite. *Id.*, 267-69. Specifically, the USTPO remarked:

Claims 30 and 38 introduce new matter as the claims recite the limitation: “wherein the nail formation does not contain any additional active agent for treating keratin.” There is no support in the specification for this limitation. The limitation of: “no additional active agent for treating keratin” was not described in the specification as filed...

* * *

Claims 30 and 38 as currently written are vague and indefinite. The claims recites the nail formation does not contain any additional active agent for treating keratin. But *the claims do not recite what type of treatment is encompassed to understand what active agents are excluded*. For example, *in the instant specification all of the active agent formulations contain water*. However, water would be expected to hydrate/moisturize the keratin. Therefore, this ingredient would appear to be excluded by the recitation the nail formation does not contain any additional active agent for treating keratin. *The metes and bounds of the claims are unclear as the scope of what is excluded* by the recitation “additional active agent for treating keratin” is unclear.

Id., 267-69 (emphasis added). Thus, the '225 patent is not the first time Patent Owner

presented vague and indefinite claim language to the USPTO and failed to support claim language with adequate written description.

Similar to before, the '225 Patent lacks disclosure of a treatment without any inactive ingredients, which is contemplated by the Challenged Claims. Similar to before, the Challenged Claims do not recite what type of treatment is encompassed and therefore there is no understanding of what ingredients and agents are excluded. Similar to before, the '225 Patent only describes examples and embodiments where water is included in the composition, but like in the prior examination, “*the metes and bounds of the claims are unclear as the scope of what*” is included and excluded in the treatment.

The issues in the present Petition are similar to the rejected claim language above in that the “treatment” is indefinite and the exclusion of water from the independent claim creates further § 112 issues. The '593 application was ultimately abandoned on November 26, 2019 for failure to respond to an office action. *Id.*, 300. The consistency issues raised herein warrant institution, in particular with regard to how the USPTO has interpreted the level of disclosure and scope attributable to Patent Owner's claims.

2. Prosecution of Hair and Skin Patents

In contrast to the '593 application's attempt to claim a method of treating nails, the issued family members of both the '593 and '158 applications all pertain

to methods of treating, bleaching, and coloring hair, or products related to hair and skin. Table 1 demonstrates this focus on hair and skin as opposed to keratin.

Table 1

<u>Patent No.</u>	<u>Claim 1 Preamble</u>	<u>Exhibit No.</u>
9,668,954	“A method for bleaching hair ...”	1006
9,326,926	“A method for bleaching hair ...”	1007
9,498,419	“A method for bleaching hair ...”	1008
9,095,518	“A method for treating hair ...”	1009
11,446,525	“A hair formulation ...”	1013
12,233,289	“A skin formulation ...”	1014

The seven patent applications listed in Table 1 all have the same inventors, assignees, and applicants as the '158 application and are all related to the '225 patent. As seen in Table 1, it is clear that the inventors, assignees, and applicants of the '158 application have historically and consistently contemplated methods and formulations of treating hair, instead of anything to do with keratin generally¹.

¹ The only two patents not explicitly limited to hair or skin are, when construed in the context of the specification, implicitly limited to hair. For example, U.S. Patent 10,639,505 claims “A keratin treatment formulation comprising an effective amount of a *binding agent*.” Binding agent is defined in the '505 patent

C. Claims

The '225 patent recites 17 claims as described above and reprinted in Appendix A, *infra*. The claims broadly claim a method of treatment that involves contacting a compound with keratin. Ex. 1001, cl. 1; Ex. 1002, ¶¶63-64.

III. STATEMENT OF PRECISE RELIEF REQUESTED

Claims 1-12 and 15-17 (“Challenged Claims”)² are unpatentable and should be canceled in view of the following grounds:

Ground	Basis
Ground I	Claims 1-12 and 15-17 lack enablement under 35 U.S.C. §112(a)

specification as used “to repair the hair,” and is consistently used in the context of binding to hair. Ex. 1012. Similarly, U.S. Patent 9,144,537 claims “A kit comprising: (a) a first formulation capable of reducing disulfide bonds *in hair* ...” Ex. 1010. Claim 1 of U.S. Patent 9,855,447 recites similar subject matter. Ex. 1011. (“A kit comprising . . . to covalently bond free thiol groups in hair.”) Although not explicitly directed to a method of treating hair, a kit comprising a component to treat hair is effectively targeting the same field of invention.

² Claims 13 and 14 expressly are limited to hair and skin respectively and therefore do not lack the same written description and enablement issues raised in this Petition with regard to the other claims that are challenged.

Ground II	Claims 1-12 and 15-17 lack written description under 35 U.S.C. §112(a)
Ground III	Claims 1-12 and 15-17 are indefinite under 35 U.S.C. §112(b)

These Grounds are supported by the expert declaration of Lisa Gallo, whose qualifications are set forth in more detail in Exhibit 1002. Ex. 1002, ¶¶1-62, 172-76.

IV. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art 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 skilled artisan may have an advanced degree in chemistry with at least two years of experience in the same field. *Id.*, ¶59.

V. CLAIM CONSTRUCTION

Claim terms are generally accorded their ordinary and customary meaning; otherwise, terms are defined by the meaning they “would have to a person of ordinary skill in the art in question at the time of the invention.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). For the purposes of this challenge, no terms need be expressly construed, and the plain and ordinary meaning of the claims as drafted governs this challenge. For example, the specification provides a number of definitions of terms as used in the specification that would inform a POSA as to the meaning of certain terms and concepts used and described in the '225 patent. Ex. 1001, 4:20-7:52. As no specific term or meaning is necessary to this proceeding, no construction is necessary. Only claim terms in controversy need to be construed, and

only to the extent necessary to resolve the controversy. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

VI. DETAILED EXPLANATION AND EVIDENCE

A. Ground I: The Challenged Claims Fail for Lack of Enablement Under §112

Section 112 mandates that the specification must “contain ... the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains ... to make and use the same.” 35 U.S.C. § 112(a). A patent’s specification “must enable the full scope of the invention without undue experimentation.” *Forte Biosciences, Inc. v. University of Massachusetts*, PGR2023-00014, Paper 45, page 23 (PTAB, June 24, 2024) (citing *Wyeth and Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013)). Generally, the more that a patent owner claims, the more they must enable via disclosure in the patent’s specification. *Amgen Inc. v. Sanofi*, 598 U.S. 594, 613 (2023).

Although it is unnecessary to repeat in the specification what is well-known in the art, the background knowledge of a POSITA cannot fill gaps in a non-enabling specification. *Enzo Life Sciences, Inc. v. Roche Molecular Systems, Inc.*, 928 F.3d 1340, 1348 (Fed. Cir. 2019). Likewise, “when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required,” and the patent fails “to meet the enablement

requirement.” *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997). In essence, where a claim “covers a broad genus without sufficient supporting examples,” it “will not be enabled.” *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1371 (Fed. Cir. 2010).

For the reasons discussed below, the Challenged Claims are not enabled by the disclosure and are invalid. Ex. 1002, ¶¶70, 119.

1. The Challenged Claims Fail for Enablement under *Amgen*

In *Amgen v. Sanofi*, the patents at issue claimed a genus of antibodies, which contained potentially millions of members that performed two specific functions. 598 U.S. at 603. The patents themselves only identified “26 antibodies that perform these two functions.” *Id.*, 602. Amgen only offered scientists two methods through which to discover the rest of the millions of antibodies claimed, namely, a “roadmap” method and a “conservative substitution” method. *Id.*, 603. Considering this severely deficient disclosure, the Supreme Court held that Amgen had not enabled the full scope of its claims covering the potentially millions of antibodies. *Id.*, 614. The Court stated that the methods described were “little more than two research assignments,” leaving others to undertake “random trial-and-error discovery.” *Id.*

A. No enablement of treating all forms of keratin

Like the patent owner in *Amgen*, Patent Owner here claims the entire genus of methods treating *all forms* of keratin in a person using a wide (and undescribed)

range of compositions. Ex. 1002, ¶¶107-09, 122. However, Patent Owner at best only enables two such species of methods, namely, treating hair keratin and treating skin keratin, and only for certain composition percentages. *Id.*, ¶124.

The '225 patent is replete with references to methods to treat hair and skin, yet it lacks even a single reference to keratin found in any other substrate, such as nails. *Id.*, ¶¶70-79. For instance, the title of the '225 patent is “Methods for Fixing Hair and Skin,” the Background section begins with an explanation that “[h]air consists of many long protein chains,” and the summary of the invention discloses “[c]ompositions, kits, and methods for repairing bonds ... in *hair* or on the *skin*.” Ex. 1001, Title, 1:40-2:27, 3:30-31.

The term “hair” even gets its own definition. *Id.*, 4:23-27. Further, the formulations of the '225 patent are described as being “concerned with treating hair or skin,” and are referred to as “formulation[s] for treating hair,” “formulation[s] for treating skin,” or “[t]he hair repair formulation.” *Id.*, 7:56-57, 20:60, 21:1, 25:5. The “Methods of Use” described “are concerned with treating hair,” and detail such methods as “Treating Damaged Hair with Free Thiol Groups,” “Chemical Treatment of Hair with a Reducing Agent,” and “Apply the Coloring Formulation to the Hair.” *Id.*, 27:62, 27:64, 28:56, 30:16. Thus, there can be no doubt that the '225 patent is directed to methods of treating hair. Ex. 1002, ¶79.

In contrast, the '225 Patent, other than in the claims and abstract, mentions

keratin only seven times, and always in the context of hair or skin (other than a reference to keratin amino acids). Ex. 1001, 2:22-31 3:41-44, 21:43. However, keratin in the human body is broader than just hair and skin – it includes keratin in one’s nails and in one’s internal organs, among other bodily areas. *See* Ex. 1004; Ex. 1002, ¶78. Yet the ’225 patent specification is silent as to keratin anywhere other than hair and skin. *Id.*, ¶¶71-72. For example, the specification deigns to define hair, yet does not define keratin, even though claim 1 purports to cover “[a] method of treating *keratin* of a person.” Ex. 1001, 36:47.

Further, each mention of keratin alone in the ’225 patent is tied to hair or skin. The background section details that “[t]reatment with peroxides used in the hair styling process results in the following reaction: $2K-S-H+H_2O \rightarrow 2-K-S-S-K+2H_2O$ (Rxn I) where ***K represents keratin in the hair.***” *Id.*, 2:17-21 (emphasis added). The specification also provides that “[k]eratin is ... a major component in skin.” *Id.*, 2:28. However, there simply is no mention of keratin alone outside of the claims or abstract without mention also of hair or skin, and there is no mention of the other parts of the body that may contain keratin. Ex. 1002, ¶¶71-72. Absent such disclosure, the ’225 patent purports to cover a genus of methods without enabling said genus. The ’225 patent thus violates “the bargain” with the public by monopolizing more than it is warranted.

B. No enablement of the full range of compositions

Not only does the specification fail to enable claim 1 to the extent that treating *all human keratin* is not enabled, but also the '225 patent fails to enable *all treatments* for keratin using the proposed structure. Claim 1 purports to broadly cover *any treatment or formulation* for keratin so long as the treatment (1) targets keratin and (2) contains the hexanediamine and maleic acid components illustrated in the claim. Ex. 1001, 36:47-63. This expansive language covers any combination of short-chain alcohol and water. Ex. 1002, ¶¶121-22. Claim 1 is written to effectively claim a range of 0-100% (wt) water, however, 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. *See* Ex. 1001, 23:30-35 (“The formulations typically contain greater than one percent (wt) water. . . and most preferably greater than 80% (wt) water.”).

The challenged dependent claims half-heartedly attempt to reign in this broad monopoly but still fail. Ex. 1002, ¶3. Claim 3 is directed to “[t]he method of claim 2, wherein the composition comprises greater than 1 wt. % water,” and claim 2 is directed to “[t]he method of claim 1, wherein the composition further comprises water and an alcohol.” Ex. 1001, 36:64-67. The specification, however, is sparse with regards to recommendations for both water and short-chain alcohol content. The lone guidance that the '225 patent discloses regarding water and alcohol concentration is:

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.

Id., 23:30-38. This disclosure is simply insufficient to warrant patent protection for *all* of the different concentrations of water and short-chain alcohol (e.g., 5% (wt) of water or 95% (wt) of alcohol) that can be used in a formulation for keratin treatment. Ex. 1002, ¶¶89-93.

Specifically, the '225 patent states an object of the invention is to provide improved conditioning and moisturizing for hair and/or skin. Ex. 1001, 3:3-26. To that end, the '225 patent describes formulations with a high water content and a low short-chain alcohol content. Ex. 1002, ¶¶89-91, 114-15. However, not all keratin substrates are treated equally. *Id.*, ¶117 (“[I]n 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.”).

A high water content and low short-chain alcohol content may be ideal for keratin in hair and skin, but a treatment for keratin in nails would require a high organic solvent concentration. *Id.*, ¶¶112-17. If one were to use a formulation ideal

for nails on hair or skin which included a high short-chain alcohol content, it would inevitably lead to “dryness, brittleness, and frizz” on hair and induce “irritation, including burning, redness, itching” in skin. *Id.*, ¶¶83, 85-86. Thus, if anything, a POSITA would be discouraged from using the methods and formulations disclosed in the '225 patent on *all* keratin-rich substrates because effective treatments must be tailored to the needs of the specific substrate. *Id.*, ¶¶117-18. Accordingly, the '225 patent specification fails to enable the full range of compositions and treatments claimed in the Challenged Claims. *Id.*, ¶¶109-19.

As in *Amgen*, where the patents at issue were invalidated as nonenabling for the vast genus of antibodies they purported to cover, so too here should the Challenged Claims of the '225 patent be cancelled for failing to enable one skilled in the art to use a “method of treating keratin of a person” to the fullest extent.

2. The Challenged Claims Also Fail for Enablement Under the Wands Factors

A patent fails the enablement requirement when its specification does not enable the claims to the full extent of the scope of the claims, without undue experimentation. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). The *Wands* factors offer guidance “to be considered in determining whether a disclosure would require undue experimentation.” *Id.* These factors include:

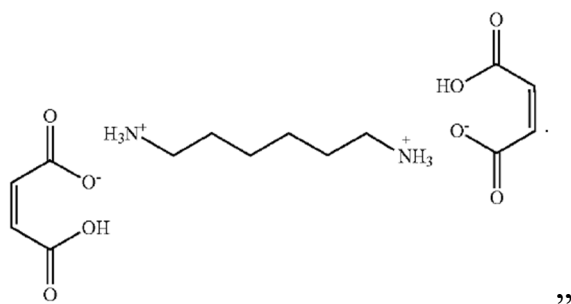
- (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working

examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the unpredictability of the art, and (8) the breadth of the claims.

Id. Here, an analysis of the various *Wands* factors leads to the same conclusion as an analysis under *Amgen*—the '225 patent claims fail for lack of enablement. Ex. 1002, ¶120; 152-57.

A. The Breadth of the Claims (Factor 8)

Contrary to the seemingly narrow title of the '225 patent, “Methods For Fixing Hair and Skin,” the Challenged Claims instead target an entire genus of treatment methods. Ex. 1001, 36:47-38:16; Ex. 1002, ¶¶121-23. Specifically, claim 1, from which claims 2-12 and 15-17 depend, is directed to “[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, cl. 1.

While claim 1 appears to encompass *all* modes of contact-based treatment of all forms of keratin, the specification is not so broad. Ex. 1002, ¶¶121, 125. The

specification explicitly states “there is a need to provide long lasting moisturizing feel, smooth feel, and manageability control to **hair** when it is dried.” Ex. 1001, 3:4-7. Moisturizing, or softening, the keratin in hair and on skin via a formulation with a relatively high water concentration is thus a desired result of the ’225 patent. *See id.*, 23:31-35 (“The formulations typically contain ... most preferably **greater than 80% (wt) water.**”) (emphasis added); Ex. 1002, ¶¶80-82.

In contrast, treating another form of keratin in the body, specifically, “broken, cracked, or weak nail[s],” focuses more on using the right **hardening** treatment that may contain aldehydes, “iodine, hydrazines, divinyl sulfone [or] dithiopyridine.” Ex. 1016, 1:41, 1:49-62. These nail treatments may utilize compositions with a lower water content and a higher short-chain alcohol content. Ex. 1002, ¶84. *See also*, Ex. 1016, 13:40-14:50 (exemplary compositions for nails described which include between 40-80 wt% alcohol and 0-20 wt % water). The claimed treatments, although targeting “keratin of a person,” are inappropriate for use on hair or skin because the use of organic solvents dries out hair and skin tissue. Ex. 1002, ¶¶83-88.

A POSITA, viewing the intrinsic record (e.g., the specification), would understand the contemplated “keratin” to be “keratin of the skin or hair” at least because of the overwhelming presence of “hair” mentions in the specification. Ex. 1002, ¶¶110-13, 121. However, “keratin” is well-known in the art to include not just keratin of the skin and hair, but also keratin of the nails, organs, tissue, oral and nasal

passages, etc. *See* Ex. 1004; Ex. 1002, ¶78. A POSITA would thus be confused as to whether the claims at issue here truly cover literally all keratin present in the human body or only keratin in the skin and hair. Ex. 1002, ¶125. Although a POSITA may deduce from the specification that keratin at least means keratin related to the human dermis, it is still unclear from the claims whether keratin includes nails, or only includes hair and skin. *Id.*

Moreover, the treatment methods for skin and hair versus nails are inapposite – skin and hair require moisturizing, while nail treatments can include moisturizing, but often also include organic solvents. *Id.*, ¶¶80-86. A method used to treat nails thus is not a suitable method to also treat hair and skin. *Id.*, ¶¶83-88. Accordingly, insofar as “keratin” is interpreted as “keratin in the skin, hair, and nails,” (or any other human keratin for that matter) the term is not enabled, lacks written description, and is indefinite because a POSITA would not recognize the treatments normally used for nails as acceptable treatments for hair and skin. *Id.*, ¶¶117-119.

As such, and in view of the allegations in patent owner’s letter, the claimed keratin of claim 1 encompasses more than simply hair and skin, and indeed, includes at least nails, internal organs, and connective tissue, among other bodily areas. *See* Ex. 1004; Ex. 1002, ¶¶78, 122. Claim 1 therefore monopolizes a method of treating *all keratin* of a person. Ex. 1002, ¶122. The breadth of this claim is unwarranted given the fact that the specification fails to describe or teach a method of treating

every instance of keratin in the human body, let alone any evidence that the breadth of the claims would provide any treatment (as required by the claims) to keratin, for example, in a human's nails. *Id.*, ¶125.

Similarly, claim 1 purports to cover a method of using *any* treatment for keratin of a person so long as the treatment incorporates the compound illustrated in the claim. As written, the treatment of claim 1 could comprise *any material or combination of materials without limitation*. While claim 2 limits the composition of claim 1's treatment to water and alcohol, it still allows for *any* combination of short-chain alcohol and water as well as *any* other materials. Ex. 1001, 36:64-65. Thus, dependent claim 2 fails to remedy this overbreadth. Ex. 1002, ¶123. Claim 16 is similarly broad and, in fact, is duplicative of claim 2. Claim 3 is directed to "[t]he method of claim 2, wherein the composition comprises greater than 1 wt. % water," and claim 2 is directed to "[t]he method of claim 1, wherein the composition further comprises water and an alcohol." Ex. 1001, 36:66-37:2. However, claim 1 simply states "a method of treating keratin of a person, the method comprising contacting the keratin with a composition comprising a compound having a chemical structure" which includes hexanediamine and two maleic acid molecules. *Id.*, 36:66-37:2.

As written, there is *no limitation* in claim 1 concerning what the claimed treatment should comprise other than the hexanediamine and two maleic acid molecules (in the exact same structure that the USPTO found too broad during the

prosecution of Olaplex's other patent applications, *see* Section II.B.1). Ex. 1002, ¶¶122-23. By its plain terms, claim 1 seeks to cover formulations with no water at all, every variety of water concentration (including from 0.01% (wt) to 99.99% (wt)) and any concentration of short-chain alcohol (including from 0.01% (wt) to 99.99% (wt)) as well as a whole gamut of combinations of components, so long as the formulation treats keratin and includes the specified chemical structures. Indeed, claim 1 would cover a treatment using a composition with the compound and short-chain alcohol alone (with no water), which would significantly harm keratin in hair. Ex. 1002, ¶85. This is a precariously broad range of claim scope for a specification that provides no insight into the preferred short-chain alcohol concentration for anything other than the narrow application of treating hair.

**B. The Nature of the Invention (Factor 4) and
Unpredictability of the Art (Factor 7)**

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. *Id.*, ¶¶138-39. Inventions within the fields of chemistry and biology, especially in vivo biology, are unpredictable. *Id.*, ¶140. As stated above in Section II.A, the specification suggests the formulation for the method of hair or skin treatment can contain up to 10 separate excipients/ingredients, each of which must be properly optimized to create an effective treatment for keratin in skin or hair. *See, e.g.*, Ex. 1001, 7:61-19:55 (binding agents), 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). Binding agents, one of the main ingredients of the claimed composition, have various properties and further components which needs be carefully selected to formulate a proper treatment, such as “lower molecular weight,” “linkers,” and “reactive moieties.” *Id.*, 8:49-51, 8:21-23, 8:22; *see also* Ex. 1002, ¶¶74-75. A linker can be one of at least 16 different atoms or “groups of atoms.” Ex. 1001, 9:24-30. One of these linker candidates, a polymer, can be any one of 26 different types or “combinations thereof.” *Id.*, 10:34-50.

The above variety of components does not even include the different kinds of reactive moieties, which further may comprise Michael acceptors, vinyl sulfones, vinyl sulfoximines, electrophilic moieties containing a leaving group, electrophilic thiol acceptors, or free radical-forming groups, or even the varying types of excipients, conditioning agents, or viscosity modifying agents. *Id.*, 11:16-19:55, 19:56-21:13, 23:13-28, 23:39-53.

With all these ingredients in mind, “a POSA with experience in hair and skin substrates in August 2013, would find the task of developing a suitable formulation to treat nail keratin very unpredictable.” Ex. 1002, ¶142. In fact, the nature of the art is unpredictable enough that, with the lack of description and working examples, a

POSITA would effectively need to start from scratch to arrive at a method of treating keratin other than in hair or skin. *Id.*, ¶¶141, 143-46. A POSITA would “consider many variables when attempting to determine the ingredients of the formulation,” and “would find it very difficult to predict the concentration of binding agent needed to provide effective” treatment of the nail. *Id.*, ¶¶143-44. Ultimately, the 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.” *Id.*, ¶144.

C. Quantity of Experimentation Necessary (Factor 1)

A POSITA, with the wide variety of complex chemical compounds to choose from and optimize and with such a broad claim as “a method of treating [all] keratin of a person,” would need to experiment thoroughly to arrive at a method of treating keratin other than in hair and skin. *Id.*, ¶¶149-53. Specifically, a POSITA “would need to essentially start from scratch in order to create a formulation effective at treating keratin” other than in hair or skin. *Id.*, ¶149. Because 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 to properly effect treatment. *Id.*, ¶¶144, 146-47, 150; *see also* Ex. 1001, 11:1-5 (“The reaction between the reactive moiety and the thiol groups may be initiated ...when the reactive moiety *contacts* a thiol group in the hair or on the skin.”) (emphasis added). Configuring a formulation which will transport an effective compound to

the keratin in the nail to properly treat the nail would require extensive experimentation and optimization of the many components enumerated in Factors 4 and 7 as well as any additional components which are specific to treating nails. Ex. 1002, ¶¶147-51.

**D. Relative Skill of Those in the Art (Factor 6) and
State of the Prior Art (Factor 5)**

The '225 patent's claims relate to a genus of methods of treating keratin using a chemical formulation comprising a variety of compounds. A POSITA thus would have a bachelor's degree in chemistry and four years of experience in cosmetic science including in hair and skin. *Id.*, ¶¶59, 126-27. Alternatively, a POSITA may have an advanced degree in chemistry with at least two years of experience in the same field. *Id.*

The relatively lower level of skill associated with an earlier-in-their-career research scientist equates to more guesswork in arriving at a method of treating *all* keratin. *Id.*, ¶¶128-30. Additionally, it is common in the industry for cosmetic companies to distinguish between “divisions that work on formulations for nails or formulations for all other cosmetically relevant substrates.” *Id.*, ¶¶128-29. This means that there is commonly little crossover between those who formulate treatments for nails and those who formulate treatments for hair and/or skin. *Id.* Accordingly, a POSITA with experience in formulating hair treatments would require additional time and experimentation to arrive at a formulation or method for

treating nails. *Id.*, ¶¶142-44. In the event a greater level of skill were adopted, such a person would have a greater understanding of the differences between hair and nails and would not have found the teachings of the '225 patent to have any pertinence to nails. *Id.*, ¶¶59-60, 71-72.

E. Amount of Direction or Guidance Presented (Factor 2) and Presence or Absence of Working Examples (Factor 3)

The specification presents eight examples of methods of treating *hair*, however, the entire specification of the '225 patent discloses no such examples of methods of treating keratin in *any other form*. See Ex. 1001, 32:11-36:44; Ex. 1002, ¶¶131, 135-36. Absent any description or disclosure of methods of treating keratin generally, there simply is no direction anywhere within the '225 patent guiding follow-on innovation toward a method of treating *all keratin*, let alone keratin in nails; such direction is necessary before a POSITA could make and used the full extent of the claimed invention. Ex. 1002, ¶¶132-34, 137.

The absence of any guidance or working examples of treating *any* given keratin-rich substrate is especially potent given the diametrically opposed objectives of treating different types of keratin substrates. Specifically, the '225 patent touts the necessity of moisturizing and conditioning hair using a formulation with a higher water content. See Ex. 1001, 3:3-8; Ex. 1002, ¶¶81, 89-90, 115. Conversely, treatments for nails focus instead on hardening the nail using a formulation with a

higher organic solvent content. *See e.g.*, Ex. 1016; Ex. 1002, ¶117. Using a method for one of the keratin substrates is not transferrable to another keratin substrate, and guidance for a method for one substrate simply does not directly translate into guidance for another substrate. Ex. 1002, ¶¶137, 146. Indeed, applying treatments suitable for hair to a nail leads to unintended and often damaging consequences. *Id.*, ¶167. The '225 patent thus fails to provide sufficient direction or working examples to enable a POSITA to make and use the claimed genus.

F. Weighing the *Wands* factors shows no enablement of the Challenged Claims

The experimentation required to arrive at a method of treating *all* keratin as claimed in the '225 patent soars beyond routine, and on balance, the *Wands* factors support a finding of no enablement for the '225 patent claims. *Id.*, ¶¶154-57.

The breadth of the claims “considers the scope of the claims as written,” and the scope in the '225 patent is expansive. *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.*, 941 F.3d 1149, 1162 (Fed. Cir. 2019). As written, claim 1 asserts sovereignty over a method of treating all keratin on a person using a formulation which may include *any* combination of water and any given short-chain alcohol, or none of either. Ex. 1001, 36:47-63; Ex. 1002, ¶¶122-23. The formulation may include up to 11 different compounds, any one of which may further be made of a variety of sub-compounds. *See* Ex. 1001, 7:60, 19:58-23:64. The various combinations of each component are numerous, further broadening claim 1's scope,

and increasing the odds that “a person of ordinary skill in the art would have been required to engage in an iterative, trial-and-error process to practice the claimed invention.” *ALZA Corp. v. Andrx Pharmaceuticals, LLC*, 603 F.3d 935, 941 (Fed. Cir. 2009). With a scope so large but a specification so lacking in guidance, “a POSA [is left] searching to find a needle in a haystack” for the right formulation that will serve in a method for treating all keratin in a person’s body. *Idenix*, 941 F.3d at 1162.

The nature of the invention is inherently unpredictable – there are numerous disclosed components and variables in the ’225 patent specification, all of which must be optimized to treat any given substrate with keratin. Ex. 1001, 7:60, 19:38-23:64; Ex. 1002, ¶¶143-44. A POSITA having a bachelor’s in chemistry and four years of industrial experience, looking to the specification for guidance, would struggle long and hard to arrive at a method for treating keratin in substrates other than hair or skin without undue experimentation. Ex. 1002, ¶¶149-51. *See also Idenix*, 941 F.3d at 1161 (parties’ testimony that the art was unpredictable indicated factor weighed in favor of non-enablement).

The ’225 patent reveals no working examples of treating keratin other than in hair, and possibly treating in the skin context. Ex. 1001, 32:11-36:33; Ex. 1002, ¶131. There is not a single example or even suggestion or vague inkling that encompasses keratin in nails or any other parts of the body, and there is zero guidance provided to a POSITA for how to arrive at a method for treating the same.

Ex. 1002, ¶¶131, 135-37. The '225 patent instead provides eight examples of a treatment for hair. Ex. 1001, 32:11-36:44. However, these are at best “only a starting point” for a POSITA seeking to create a method of treating nails or other keratin rich substrates, and a starting point or “a direction for further research” is insufficient to qualify as specific guidance necessary for enablement. *ALZA*, 603 F.3d at 341 (quoting *Genentech*, 108 F.3d at 1366). Further, when “working examples are present but are ‘very narrow, despite the wide breadth of the claims at issue,’ this factor weighs against enablement.” *Idenix*, 941 F.3d at 1161 (quoting *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1374 (Fed. Cir. 1999)).

Accordingly, whether analyzing the '225 patent specification under *Amgen* for enablement generally or under *Wands* for undue experimentation, the conclusion is the same—the '225 patent fails to enable a POSITA to make and use the full scope of its claims without undue experimentation.

Thus, the '225 patent fails to use “such full, clear, concise, and exact terms as to enable any person skilled in the art” to make the full scope of the claims. 35 U.S.C. §112(a). Accordingly, the '225 patent claims must fail for lack of enablement. specification fails to enable the full scope of the Challenged Claims.

B. Ground II: The Challenged Claims Lack Written Description

Even if the Challenged Claims were enabled, the '225 patent fails for lack of written description and the Challenged Claims warrant cancellation as a result. *See*

Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy's Lab's Inc., 923 F.3d 1368, 1382 (Fed. Cir. 2019) (“[T]he fact that an invention may be enabled does not mean it is adequately described, and vice versa.”). Whereas enablement is directed to enabling a POSITA to make and use the claimed invention, the written description requirement exists to “show that the inventor actually invented the invention claimed.” *Ariad Pharmaceuticals, Inc.*, 598 F.3d at 1351.

An inventor must show they possessed their invention by sufficiently describing it. *Id.*, 1345. Where a Patent owner does not sufficiently disclose or describe their invention, they have not proven they possessed it at the time of the application. *Id.*, 1351. *See also Columbia Ins. Co. v. Simpson Strong-Tie Co.*, No. 2021-2045, 2023 WL 2733427 at *3 (Fed. Cir. Mar. 31, 2023) (“In a patent system which allows claim amendments and continuation applications long after an initial application is filed, the written description requirement serves an important purpose: to ensure that the patent owner may only exclude others from what they had actually invented ***as of the priority*** date.”) (emphasis in original).

Although there is no bright line rule dictating how many species a specification must disclose to properly describe a genus claim, the Patent owner must still disclose “a representative number of species falling within the scope of the genus or structural features common to the members.” *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1363 (Fed. Cir. 2011) (quoting *Ariad*

Pharmaceuticals, Inc., 598 F.3d at 1350). “[E]xamples are not always required to satisfy the written description requirement,” but “the lack of any disclosure of examples may be considered when determining whether the claimed invention is adequately described.” *Id.*, 1364.

The ’225 patent claims fail for written description both because of the lack of disclosure of sufficient species (*see* Ex. 1002, ¶¶94-106) and because of this case’s similarity to Federal Circuit precedent.

1. The ’225 Patent Fails to Disclose Sufficient Species Within the Broadly Claimed Genus

Claim 1 purports to cover “a method of treating [all] keratin of a person,” yet arguably only recites and describes methods of treating hair or skin. *See* Ex. 1001, 7:56-57, 25:15-17, 27:62-63, 32:13-36:44; *see also* Ex. 1002, ¶¶70-72, 95-97. Keratin, although lacking a definition in the ’225 patent, involves more than just hair and skin, but also nails, eye lashes, and internal organs among other body parts. *See* Ex. 1004; Ex. 1002, ¶78. Yet the ’225 patent is silent as to methods of treating any other form of keratin in a person’s body besides the hair and skin. Ex. 1002, ¶¶78-79. The ’225 patent mentions hair 485 times and skin 35 times, yet keratin appears only seven total times, and nails, organs, eyelashes, and other forms of keratin are not mentioned at all. *See generally* Ex. 1001; *see also* Ex. 1002, ¶¶96-98. The disparity in instances between hair and keratin alone shows that this patent does not describe methods of treating *keratin* – it describes methods of treating keratin in

hair, and perhaps also skin. Ex. 1002, ¶¶77-79, 98-101.

Further, the '225 patent specification contains eight working examples, and all are methods of treating hair. Ex. 1001, 32:11-36:44. Despite the inventors' apparent ability to produce working examples, the specification neither discloses nor suggests any examples or methods of treating any form of keratin other than hair and skin. Ex. 1002, ¶¶135-36. This "lack of any disclosure of examples," *Boston Scientific Corp.*, 647 F.3d at 1364, is telling – if the inventor had possession of the full genus of methods of treating keratin, they would have described "the genus throughout its scope." *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1299 (Fed. Cir. 2014). The written description requirement is clear though: "[w]ith the *written description* of a genus ... merely drawing a fence around a perceived genus is not a description of the genus." *Id.*, 1300. One must instead "show that one has truly invented the genus, i.e., that one has conceived and described sufficient representative species encompassing the breadth of the genus." *Id.* Anything less, like the '225 patent at issue here, provides "only a research plan, leaving it to others to explore the unknown contours of the claimed genus." *Id.* See also *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1124 (Fed. Cir. 2008) ("[T]o satisfy the written description requirement for a claimed genus, a specification must describe the claimed invention in such a way that a person of skill in the art would understand that the genus that is being claimed has been invented,

not just a species of the genus.”).

It may be that the inventors did not truly invent a method of treating all keratin until *after* the filing date; in such a case, it would be physically impossible for Patent Owner to sufficiently describe their invention as of the time of filing, and it would explain why such description is lacking here. *See Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1255 (Fed. Cir. 2004) (“Because chimeric antibody technology did not even exist at the time of the 1984 filing, the record conclusively supports that the Chiron scientists did not possess and disclose this technology in the February 1984 filing.”). However, the analysis of the written description requires looking back to the originally filed priority specification to see whether sufficient disclosure establishes that the inventor had in their possession the scope of the later proffered invention. No such disclosure exists in the as-filed priority document suggesting a method of treating nails. *See* Ex. 1017 (containing no disclosure of nails in Application No. 14/257,056).

Not only does the ’225 patent specification fail to sufficiently describe species of keratin to be treated, but it also fails to describe a sufficient number of species of methods for treating keratin as proposed in claim 1. As mentioned in Section VI.A.1, claim 1 broadly claims any composition involved in *treating* keratin, so long as the treatment involves hexanediamine and maleic acid structures. Ex. 1001, 36:46-63; Ex. 1002, ¶122. This includes treatments with no water content, even when the

specification clearly suggests the absolute need for water in a formulation meant to moisturize and condition hair and skin. Ex. 1001, 23:29-35. Thus, a treatment with *no water whatsoever* is specifically not described by this specification, and claim 1 fails for written description as a result. *See also Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 926 (Fed. Cir. 2004) (“[T]he inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods.”)

This is not a case where Patent Owner has sought to only claim that which is “clearly described in his specification.” *Snitzer v. Etzel*, 465 F.2d 899, 902 (C.C.P.A. 1972). “[T]here would seem to be little doubt that the literal description of a species provides the requisite legal foundation for claiming that species.” *Id.* Instead, Patent Owner here seeks to claim an entire genus without disclosing sufficient species to warrant such broad patent protection. This course of action is prohibited by the written description requirement and the Challenged Claims as a result.

2. The ’225 Patent Fails for Written Description under Federal Circuit Precedent

Federal Circuit precedent as elucidated in *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.* dictates that the ’225 patent claims be cancelled for lack of written description.

Where a patent attempts “to claim every [species] that would achieve a desired

result,” but the patent specification does “not describe representative examples to support the full scope of the claims,” the claims likely fail for lack of written description. *AbbVie Deutschland GmbH & Co.*, 759 F.3d at 1301. In *AbbVie*, the “claimed invention [was] a class of fully human antibodies that [were] defined by their high affinity and neutralizing activity to ... a known antigen,” but the contested patents did “not disclose structural features common to the members of the claimed genus.” *Id.*, 1299. The patents at issue were directed to a genus which “cover[ed] structurally diverse antibodies,” but the specifications “only describe[d] structurally similar antibodies derived from [a common source].” *Id.*, 1300. The Federal Circuit upheld the jury’s finding of invalidity for lack of written description because “the described species [were] all of the similar type and d[id] not qualitatively represent other types of antibodies encompassed by the genus.” *Id.*

Similarly, here too, the ’225 patent seeks to claim “[a] method of treating keratin of a person” without sufficiently describing the different types of keratin to be treated or how treatment may vary, if at all, between different types of keratin (e.g., nails and hair). Ex. 1001, cl. 1. No mention is made of the different properties among the species of keratin-bearing substrates, and no examples described of methods of treating, for example, nails or eyelashes. No description at all is provided of experiments performed wherein the inventors varied the different concentrations of short-chain alcohol and water to arrive at the broadly claimed method.

Accordingly, just as in *AbbVie*, so too here, the claims must fail for lack of written description.

In a recent case before the Federal Circuit, the Court affirmed an ITC finding of inadequate written description where the patent owner claimed both carbon-block and non-carbon-block filters, but only disclosed carbon-block filter examples. *Brita LP v. ITC*, Case No. 24-1098, at 9 (Fed. Cir., October 15, 2025). Specifically, the patent at issue claimed “any filtration media type without activated carbon and a lead scavenger,” including non-carbon block filters. *Id.* However, the specification “describe[d] only a single type of filter media that can meet the claimed ... factor – carbon block.” *Id.* The only working examples that met the claim requirements were “those using carbon-block filter media,” and the “only types of filters that are illustrated in the figures are carbon blocks.” *Id.* The court agreed with the Commission that the “patent’s disclosure [did] not demonstrate possession of non-carbon-block filter media.” *Id.*, 12.

So too, in this case, Patent Owner has failed to demonstrate they possessed a method for treating keratin other than in hair and nails at the time of filing. The specification demonstrates eight working examples that used hair as samples, yet discloses no working examples showing treatments for nails or other keratin-rich substrates. Ex. 1001, 32:11-36:44. The patent describes a present need in the art for treating, moisturizing, conditioning, and repairing keratin in hair and skin yet

elucidates no need or object to treat keratin elsewhere in the body. Ex. 1001, 3:3-26. The specification fails to distinguish the different types of keratin yet claims to provide a method for treating *all* keratin on the human body. This lack of disclosure equates to an inadequate written description under Federal Circuit precedent.

For at least these reasons, the Challenged Claims lack adequate written description and accordingly should be canceled.

C. Ground III: The Challenged Claims Are Indefinite

The definiteness requirement of Section 112 mandates that a patents' claims "particularly point[] out and distinctly claim[] the subject matter which the inventor ... regards as the invention." 35 U.S.C. §112(b). Where a patent's claims fail to inform a POSITA with reasonable certainty about the scope of the invention, the patent is invalid. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). The claims must "be sufficiently definite to inform the public of the bounds of the protected invention ... [o]therwise, competitors cannot avoid infringement." *Halliburton Energy Servs. v. M-ILLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008). Claims are "indefinite ... where a person of ordinary skill in the art [can] not determine the bounds of the claims, i.e., the claims [are] insolubly ambiguous." *Id.* Although "some modicum of uncertainty" is permitted in interpreting patent claims, the specification must still "provide objective boundaries for those of skill in the art." *Id.*, 909; *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014).

Here, such objective boundaries in the '225 patent specification do not exist.
Ex. 1002, ¶¶158-71.

1. “Keratin of a Person” is Indefinite

If “keratin of a person” is interpreted instead to mean *all keratin in the human body*, then the phrase is indefinite because no such definition lies in the '225 patent specification and the patent lacks any direction or understanding of what type of keratin is contemplated.

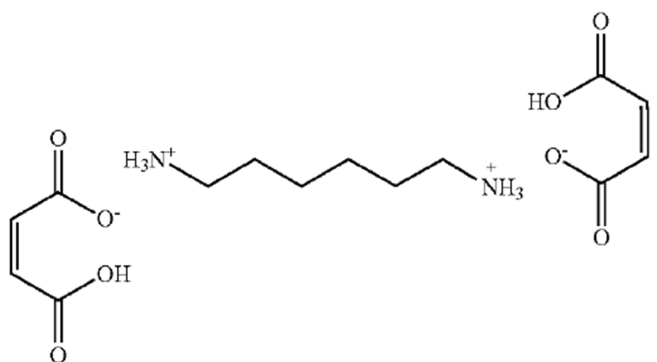
Keratin “of a person” encompasses more than just keratin in hair or keratin in nails, it includes both, as well as keratin in the organs, in the various layers of the skin, and more. *See* Ex. 1004; Ex. 1002, ¶¶78, 161. Claim 1, then, is not just amenable to multiple interpretations, but is simply ambiguous for lack of clarity as to which keratin-rich substrate is intended. Ex. 1002, ¶¶160-62. As stated in Section VI.A., *all* keratin-rich substrates cannot be treated using one universal method, yet that is exactly what claim 1 purports to do without properly defining “keratin.” *See Id.*, ¶¶147, 150. A POSITA, viewing the claims “in light of the specification delineating the patent,” could not be reasonably sure as to which kind of keratin-rich substrate claim 1 is directed towards. *Nautilus*, 766 F.3d at 901; Ex. 1002, ¶¶160, 169.

The delineations of “keratin” in the '225 patent point then, if anywhere, to a meaning synonymous with “keratin in the hair of a person” in the context of the '225

patent specification and prosecution history. Ex. 1002, ¶¶93. Should “keratin of a person” be construed to mean “*all keratin* of a person,” then the term is vague, ambiguous, and indefinite. *Id.*, ¶¶159-61.

2. “Treating” is Indefinite

As mentioned above in Section II.B.1, “treating” as used in claim 1 is similarly too broad to clearly inform a POSITA what the metes and bounds of the claims are. *Id.*, ¶163. Specifically, *the ’225 patent discloses no treatment* or method of treatment *that does not involve multiple ingredients*. Contrary to this narrow disclosure, claim 1 broadly purports to cover “a method of *treating* keratin of a person” without appropriately limiting the treatment to include such ingredients as water. Ex. 1001, 36:47-63. As stated above in Section VI.A.2, Claim 1 purports to cover “a method of *treating* keratin of a person, the method comprising contacting the keratin with a composition comprising a compound having a structure of”:



Id., cl. 1.

Under the language of claim 1, the treatment may comprise *any additional*

components as well as combinations and concentrations of components, so long as the treatment uses the hexanediamine and maleic acid molecules illustrated. Ex. 1002, ¶168. The '225 patent specification specifically explains that the formulations disclosed for “treating” hair can contain up to 11 separate ingredients, such as diluents and excipients (*see* Ex. 1001, 7:60, 19:58-23:64), but provides no concrete boundaries for what ***must*** and ***must not*** be included for the treatment to be effective.

Further, “the formulations ***typically*** contain one or more cosmetically acceptable excipients,” such as water, and “water is the ***preferred*** diluent.” *Id.*, 9:57-58) (emphasis added), 23:31 (emphasis added). Language such as “typically” and “preferred” strongly suggests that components like water are necessary for the method of “treating” keratin to even work but claim 1 again makes no mention of the necessity of water, let alone any other ingredients. Rather, the specification simply leaves definition to the POSITA to read the inventor’s minds for what was intended by “treating” at the time of filing.

Absent appropriately defined bounds, such as limiting claim 1 by including water as an active ingredient, a POSITA has no idea what components to include or exclude to even practice the method of claim 1 let alone avoid infringing the '225 patent in follow-on innovation. Ex. 1002, ¶¶164-70. Accordingly, “treating” as used in claim 1 is indefinite.

VII. MANDATORY NOTICES

A. Real Party-in-Interest Under 37 C.F.R. §42.8(b)(1)

The real party-in-interest is Wella Operations US, LLC. No unnamed entity is funding, controlling, or otherwise has an opportunity to control or direct this Petition or Petitioner's participation in any resulting PGR.

B. Related Matters Under 37 C.F.R. §42.8(b)(2)

Petitioner is not aware of any related matters that would affect or be affected by this proceeding.

C. Lead and Back-Up Counsel Under 37 C.F.R. §42.8(b)(3)

Petitioner designates lead and back-up counsel as noted below. A Power of attorney pursuant to 37 C.F.R. §42.10(b) accompanies this Petition.

Lead Counsel	Back-Up Counsel
Jason A. Engel (Reg. No. 51,654) jason.engel@klgates.com K&L GATES LLP 70 West Madison Street, Suite 3300 Chicago, IL 60602 Tel: (312) 807-4207 Fax: (312) 827-8145	Erik J. Halverson (Reg. No. 73,552) erik.halverson@klgates.com K&L GATES LLP 4 Embarcadero Center, Suite 1200 San Francisco, CA 94911 Tel: (415) 882-8238 Fax: (312) 827-8145

D. Service Information Under 37 C.F.R. §42.8(b)(4)

Please address all correspondence to the lead and back-up counsel at the addresses shown above. Petitioner consents to service by email at the addresses of lead and back-up counsel shown above.

VIII. GROUNDS FOR STANDING

Pursuant to 37 C.F.R. §42.204(a), Petitioner certifies that the '225 patent is available for PGR and that Petitioner is not barred or estopped from requesting a post-grant review challenging the patent claims on the grounds identified in this petition. Petitioner further certifies that (1) neither Petitioner nor any of its privies own the '225 patent; and (2) neither Petitioner nor any of its privies have filed a U.S. civil action challenging the validity of any claim of the '225 patent. This Petition was filed within nine months of the '225 patent issuing. The '225 patent is subject to the Leahy-Smith America Invents Act ("AIA") and thus eligible for PGR because at least one claim in a patent to which the '225 patent claims priority has an effective filing date after the effective date of the AIA.

IX. CONCLUSION

The Challenged Claims should be canceled for the reasons discussed above.

Respectfully submitted,

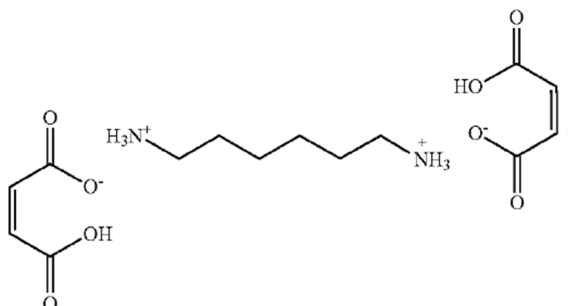
Dated: November 4, 2025

By: /Erik Halverson/
Erik J. Halverson (Reg. No. 73,552)
erik.halverson@klgates.com
K&L GATES LLP
4 Embarcadero Center, Suite 1200
San Francisco, CA 94911
Tel: (415) 882-8238
Fax: (312) 827-8145

Counsel for Petitioner
Wella Operations US LLC

APPENDIX A: CLAIM LISTING

1. 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:



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

11. The method of claim 1, wherein the compound binds to a free thiol in the keratin.

12. The method of claim 1, wherein the compound binds to the keratin through a covalent bond.

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.

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.

15. The method of claim 1, wherein the composition comprises 0.01 wt.% to 25 wt.% of the compound.

16. The method of claim 1, wherein the composition consists of the compound, water, and an alcohol.

17. The method of claim 1, wherein the composition has a pH of 5 to 8.

CERTIFICATION UNDER 37 C.F.R. §42.24(d)

Pursuant to 37 C.F.R. §42.24(a)(1)(ii), the undersigned hereby certifies that the foregoing PETITION FOR POST-GRANT REVIEW contains 10,181 words, excluding the parts of this petition that are exempted under 37 C.F.R. §42.24(a), as measured by the word-processing system used to prepare this paper.

/Erik J. Halverson/
Erik J. Halverson (Reg. No. 73,552)
erik.halverson@klgates.com
K&L GATES LLP
4 Embarcadero Center, Suite 1200
San Francisco, CA 94911
Tel: (415) 882-8238
Fax: (312) 827-8145
Counsel for Petitioner
Wella Operations US LLC

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e) and 42.205(a), the undersigned certifies that on November 4, 2025, a copy of the foregoing **Petition for Post-Grant Review, Petitioner's Power of Attorney, and Exhibits 1001-1017** were served by FedEx Priority Overnight on the correspondence address of record indicated in the Patent Office's Patent Center system for U.S. Patent No. 12,214,225:

Norton Rose Fulbright US LLP
98 San Jacinto Blvd
Suite 1100
Austin, TX 78701
UNITED STATES

Dated: November 4, 2025

By: /Erik J. Halverson/
Erik J. Halverson