BoxInterferences@uspto.gov
Tel: 571-272-7822

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

The General Hospital Corp.
(Inventors: Dilip Paithankar, Richard Dean Blomgren, Richard Rox Anderson, William A. Farinelli, Apostolos G. Doukas, and Gerard van Hamel Platerink)

Junior Party
(Patent 13/789,575),

v.

Sienna Biopharmaceuticals, Inc.
(Inventors: Todd James Harris and Alice Ann Chen Kim)

Senior Party
(Patent 8,821,941).

Patent Interference No. 106,037 (DK)
(Technology Center 1600)

DECISION ON MOTIONS
37 C.F.R. § 41.125(a)

Before RICHARD E. SCHAFER, SALLY GARDNER LANE, and DEBORAH KATZ, *Administrative Patent Judges*.

KATZ, *Adminstrative Patent Judge*.

I. Introduction

A.

Junior Party, The General Hospital Corporation ("GHC")[1] suggested this interference based on claims 65-67 of its involved application 13/789,575 ("the '575 application").

Senior Party, Sienna Labs, Inc. ("Sienna") is involved based on all claims (1-10) of its patent 8,821,941 ("the '941 patent").

The parties claim methods using particles on a nanometer size scale – "nanoparticles" – to damage hair follicles in order to remove hair or reduce its growth. The nanoparticles absorb light and generate plasmon resonance at a desired wavelength in order to heat the hair follicle and damage it. (*See* '941 patent at 2:57-61.) The parties' claimed methods use a composition comprising particles ("unassembled plasmonic nanoparticles") that have a conductive metal portion and are coated (for example with polyethylene glycol ("PEG")) to facilitate removal from the skin. First, the composition is applied to the skin so that the nanoparticles can enter the hair follicle. Then, excess composition is removed, leaving the nanoparticles in the hair follicle. The nanoparticles are then irradiated with an infrared light to thermally damage the follicle.

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[1] GHC reports that Sebacia, Inc. has certain rights through a license to the inventions of GHC's application 13/789,575. (Paper 13.)

GHC claim 65 is representative of GHC's involved claims 65-67. Claim 65 recites:

> A method of localizing thermal damage to a hair follicle, comprising:
> applying a composition to a skin surface,
> wherein said composition comprises a plurality of unassembled plasmonic nanoparticles,
> wherein the unassembled plasmonic nanoparticles comprise a conductive metal portion,
> wherein the conductive metal portion comprises gold,
> wherein the unassembled plasmonic nanoparticles have a diameter of about 150 nm,
> wherein the unassembled plasmonic nanoparticles comprise a coating that coats the conductive metal portion, wherein said coating facilitates selective removal from the skin surface,
> wherein the coating comprises polyethylene glycol (PEG),
> wherein the unassembled plasmonic nanoparticles have a concentration of about 6.6×10^{11} particles per ml of the composition, wherein said concentration is sufficient to, after exposure to irradiation, induce thermal damage in the hair follicle;
> distributing the composition from the skin surface to the hair follicle to target the hair follicle;
> selectively removing the composition from the skin surface, while leaving the composition localized within the hair follicle; and
> irradiating the composition with an infrared light source thereby inducing a plurality of surface plasmons in said unassembled plasmonic nanoparticles,
> wherein the induction of the surface plasmons generates thermal damage to the hair follicle for at least one of hair removal or hair growth reduction.

(GHC Clean Copy of Claims, Paper 14.)

B.

Sienna argues in its Motion 1 that GHC's '575 application lacks sufficient written description support for claims 65-67 under 35 U.S.C. § 112, first paragraph. We grant Sienna Motion 1.[2]

Contingent on the grant of Sienna Motion 1, GHC requests the addition of proposed claim 74 to its involved '575 application in its Responsive Motion 4. We deny GHC Responsive Motion 4.

Both parties also argue that evidence relied upon by the other should be excluded. (*See* Sienna Motion Miscellaneous Motion 3, Paper 250; GHC Miscellaneous Motion 8, Paper 304.) To the extent we rely on the argued evidence, we discuss the arguments for exclusion below.

Because of our holding that GHC does not have written descriptive support for the subject matter it essentially copied from Sienna's patent, GHC has an insufficient basis to challenge Sienna's right to its claimed subject matter. Therefore, Sienna lacks standing in this interference and we terminate the interference without consideration of any other substantive motions.[3]

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[2] Sienna requests oral argument. (Paper 251.) After review of the parties' briefs and supporting evidence, oral argument is not necessary.

[3]GHC also filed Motion 1 for benefit of a provisional application (Paper 151); Motion 2, challenging Sienna's claims under 35 U.S.C. § 112, first paragraph, for lack of written description and an enabling disclosure (Paper 152); and Motion 3 arguing that Sienna is not entitled to the benefit accorded to it (Paper 153). Sienna also filed Motion 2, aruing for the benefit of provisional applications (Paper 85).

II. Sienna Motion 1 – Unpatentability under 35 U.S.C. § 112, first paragraph

Sienna argues that all of GHC's involved claims lack written description under 35 U.S.C. § 112, first paragraph. (Sienna Motion 1, Paper 84.) Whether the description requirement is met is a question of fact. *Vas-Cath Inc. v. Mahurkar,* 935 F.2d 1555 (Fed.Cir.1991). Specifically, the test for written description under 35 U.S.C. § 112, first paragraph, "is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc., v. Eli Lilly & Co.*, 598 F3d 1336, 1351 (Fed. Cir. 2010).

Sienna argues that GHC lacks written description for two limitations that are present in each of claims 65-67: (1) a "concentration of about 6.6 X 10^{11} particles per ml of the composition" and (2) "unassembled plasmonic nanoparticles."

A.

GHC relies on the testimony of Ivan J. Dmochowski. (*See, e.g.* Fourth Declaration of Ivan J. Dmochowski ("Fourth Dmochowski Decl.") Exh. 2093.) Dr. Dmochowski testifies that he received a Ph.D. in Bioinorganic Chemistry and is currently a Professor of Chemistry at the University of Pennsylvania. (Declaration of Ivan J. Dmochowski Decl. ("First Dmochowski Decl."), Exh. 2026, at ¶¶ 1-2.) He testifies further that he has studied plasmonic nanoparticles since 2003 and is currently working on the interaction of gold nanoparticles with a biological protein. (*Id.* at ¶ 4.) Dr. Dmochowski's *curriculum*

vitae indicates that he has authored many peer-reviewed publications and has received numerous research awards, honors and grants. (*See* Second Declaration of Ivan J. Dmochowski, Exh. 2025, at ¶ 2, citing Dmochsowksi *curriculum vitae*, Exh. 2027.) We find Dr. Dmochowski to be qualified to testify about nanoparticles.

Sienna relies on the testimony of Andrea Tao. Ph.D. (Exh. 1002). Dr. Tao testifies that she has worked in the field of nanomaterials chemistry, specifically plasmonic nanoparticles, for 14 years, currently as a Professor of Engineering and Principal Investigator of the Nanoscale Colloids and Interfaces Laboratory in the Nanoengineering Department at the Unversity of California San Diego. (Declaration of Andrea Tao, Ph.D. ("Tao Decl."), Exh. 1002, at ¶¶ 6-7.) Dr. Tao testifies that she received a Ph.D. in Chemistry from the Unversity of California Berkley, where she worked on the synthesis and assembly of inorganic nanomaterials, including plasmonic nanoparticles, and worked as a postdoctoral fellow at the University of California Santa Barbara in the Department of Molecular, Cellular, and Developmental Biology. (*Id.* at ¶¶ 10-11.) She also testifies that she has received numerous research awards and authored many peer-reviewed publications. (*Id.* at 8 and 13; *see* Tao *curriculum vitae*, Exh. 1003.)

GHC argues that Dr. Tao is not qualified to testify as an expert in this interference because she lacks experience using nanoparticles in cosmetic, diagnostic, and/or therapeutic procedures.[4] (*See* GHC Opp. 1, Paper 222, at 7:23-

[4] We note that GHC's witness, Dr. Dmochowski, does not testify about any

8:27 and 12, n.5; *see also* GHC Motion to Exclude, Paper 304, at 2:23-3:9.) We do not agree. Dr. Tao's experience and credentials indicate that she has significant experience with nanoparticles. Thus, she is qualified to testify about nanoparticles in general, even if she may not be qualified to testify about cosmetic, diagnostic, or therapeutic procedures.

We note that all witnesses must disclose the underlying facts or data on which their opinion is based in order for significant weight to be accorded to the opinion. *See* 37 C.F.R. § 41.158(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.") Thus, we evaluate the weight to be accorded to Dr. Tao's testimony based on the sufficiency of the evidence supporting the underlying facts.

B.

We first take up Sienna's arguments regarding the lack of written description for GHC's claim phrase "about 6.6 X 10^{11} particles per ml" under 35 U.S.C. § 112, first paragraph. (Sienna Motion 1, Paper 84, at 14:24-23:22.)

Sienna argues that the term "about" in GHC's claims is properly construed to mean "within 10% of." Sienna cites to the use of the term "about" in Sienna's specification and to its definition in GHC's specification in support. Specifically, GHC's specification provides:

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experience in the field of hair removal or reduction in growth, acne treatment, or any other cosmetic treatment. (*See* Declaration of Ivan J. Dmochowski, Exh. 2026, at ¶¶ 1-7.)

> Unless specifically stated or obvious from context, as used herein, the term "about" is understood as within a range of normal tolerance in the art, for example Within 2 standard deviations of the mean. About can be understood as within 10%, 9%, 8%, 7%, 6%, 5%, 4%, 3%, 2%, 1%, 0.5%, 0.1%, 0.05%, or 0.01% of the stated value. Unless otherwise clear from context, all numerical values provided herein are modifed by the term about.

(GHC '575 application, Exh. 1024, at ¶ 43.) Dr. Tao testifies that Sienna's specification also reflects this range of variation. (*See* Tao Decl., Exh. 1002, at ¶ 72.) We agree that the construction of "about" provided in both parties' specifications is most reasonably "within 10%."[5]

In light of this construction, Sienna argues that the proper construction of GHC's claim term "about 6.6 X 10^{11} particles per ml" is a range of at most from 5.94 x 10^{11} to 7.26 x 10^{11} particles per ml. (Sienna Motion 1, Paper 84, at 15:11-17:28, citing Tao Decl., Exh. 1002, at ¶ 79. [6]) GHC does not argue to the contrary.

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[5] As Sienna notes (Sienna Reply 1, Paper 230, at 3:18-22), Dr. Dmochowski testifies that becaue the optical density of formulation F78 is reported with two different O.D.s in two parts of GHC's specification, one of skill in the art would have considered a 20% variation to be acceptable. (*See* (Fourth Dmochowski Decl., Exh. 2093, at ¶¶ 15 and 16.) GHC does not rely on this testimony or argue that Dr.Tao's determination of "about" as being a 10% variation is incorrect. Accordingly, we do not consider Dr. Dmochowski's testimony about this issue in our analysis.

[6] In its Motion to Exclude, GHC argues that Dr. Tao's testimony regarding the meaning of "about" is not supported and should be excluded. (*See* GHC Motion 8, Paper 304, at 6:9-12.) We disagree because Dr. Tao relies on GHC's and Sienna's

Both Sienna and GHC agree that GHC's specification does not disclose the recited, or any, concentration in particles per ml. (*See* Sienna Motion 1, Paper 84, at 15:1-3; GHC Opp. 1, Paper 222, at App'x 2, p. 3, response to Sienna Material Fact 11.) Instead, GHC's specification provides the "optical density" ("O.D.") of solutions of nanoparticles. (*See, e.g.* GHC '575 appl., Exh. 1024, at ¶¶ 100 (Example 4) and p. 9, Table 1 (Example 9).) According to Sienna, when the O.D. measurements reported in GHC's specification are properly converted,[7] they do not indicate a concentration of about 6.6 x 10^{11} particles per ml. (Sienna Motion 1, Paper 84, at 18:8-22:2.)

Sienna relies on the testimony of Dr. Tao to support its argument. According to Dr. Tao, the proper extinction coefficient to convert an O.D. measurement to a concentration is 4.2 because of the wavelength used. (Sienna Motion 1, Paper 84, at 18:24-21:16, citing Tao Decl., Exh. 1002, at ¶¶ 87-89.) Dr. Tao testifies that using the correct extinction coefficient for the O.D. reported in GHC's Example 4 (250 O.D.) results in a concentration of 7.77 x 10^{11} particles per ml results. (*Id.*) But 7.77 x 10^{11} particles per ml falls outside the construed meaning of "about 6.6 x 10^{11} particles per ml" or 5.94 x 10^{11} to 7.26 x 10^{11}

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specifications for her testimony. (*See* Tao Decl., Exh. 1002, at ¶¶ 72 and 74.)

[7] Sienna also argues that conversion of O.D. meaurements is merely an estimate of the concentration of nanoparticles. (Sienna Motion 1, Paper 84, at 18:25-19:2.) Although Sienna relies on the testimony of Dr. Tao in support, we are not persuaded because Dr. Tao does not explain her opinion. (*See* Tao Decl., Exh. 1002, at ¶84.)

particles per ml. Dr. Tao testifies further that when the O.D. measurements reported in Example 9 of GHC's specification (275 and 300 O.D.) are properly converted to concentrations (8.53 x 10^{11} and 9.31 x 10^{11} particles per ml, respectively), they fall even further outside the range claimed by GHC. (*See* Tao Decl., Exh. 1002, at ¶ 91.)

GHC does not argue that Dr. Tao's determination of the extinction coefficient or her calculations are incorrect. (*See* GHC Opp. 1, Paper 222, at 19:4-20:23.) Nor does GHC argue or direct us to evidence showing that the concentration recited in claims 65-67 is supported by a specific optical denisity expressly recited in GHC's specification.

When it suggested this interference, GHC relied on Dr. Dmochowski's original testimony that the claimed concentration is supported by O.D.s reported in Table 1 of GHC's specification using the extinction coefficient of 5.5. (*See* First Dmochowski Decl., Exh. 1026, at ¶ 51.) Dr. Tao's testimony to the contrary is supported by Jain[8] (Exh. 1012) and by the references in GHC's specification to pulsed laser irradiation at 800 nm, the wavelength she used to determine the extinction coefficient of 4.2 in light of the teachings in Jain. (*See* Tao Decl., Exh. 1002, at ¶¶ 85-87.) Accordingly, we credit Dr. Tao's testimony over Dr. Dmochwoski's original testimony for the correct extinction coefficient and

[8] Jain et al., "Calculated Absorption and Scattering Properties of Gold Nanoparticles of Different Size, Shape, and Composition: Applications in Biological Imaging and Biomedicine," 110 J. Phys. Chem. 7238 (2006) (Exh. 1012).

calculation of nanoparticle concentration. In the absence of arguments to the contrary, we are persuaded that the correct conversion of the O.D. measurements reported in Examples 4 and 9 of GHC's specification do not fall within GHC's claim term "about 6.6 X 10^{11} particles per ml."

Instead of arguing that Dr. Tao is wrong, GHC argues that its claim term is supported by the range of concentrations of nanoparticles of at least 1 x 10^{11} to some value greater than 9.31 x 10^{11} and by disclosure of at least five data points with that range[9] (4.10 x 10^{11}, 4.46 x 10^{11}, 7.77 x 10^{11}, and 8.55 x 10^{11}) in GHC's specification. (GHC Opp. 1, Paper 222, at 19:21-20:23, citing GHC '575 appl., Exh. 1024, at ¶¶ 18, 100, 103, and p. 9, Table 1.) According to GHC, because its claimed concentration is encompassed by the range of optical densities disclosed in the specification, one of skill in the art would have recognized that the inventors described the claimed concentration.

We are not persuaded by GHC's argument. "[O]ne skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims." *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000). GHC fails to direct us to evidence that one skilled in the art would have understood that the specific concentration of about 6.6 x 10^{11} is the invention described in GHC's specification. GHC does not identify any guides, or "blaze

[9] Although GHC cites to paragraphs 14-66 of Dr. Dmochowski's Fourth Declaration, it is not clear from his declaration or GHC's brief how the five data points were determined.

marks," that would direct one skilled in the art to this particular concentration of nanoparticles. *See In re Ruschig*, 379 F.2d 990, 994 (C.C.P.A. 1967) ("Specific claims to single compounds require reasonably specific supporting disclosure and while we agree with the appellants, as the board did, that naming is not essential, something more than the disclosure of a class of 1000, or 100, or even 48, compounds is required."). GHC's relatively narrow range of "about 6.6 x 10^{11} particles per ml" is not readily discernible in the open-ended range of "at least 1 x 10^{11} to some value greater than 9.31 x 10^{11}" that GHC argues is described in its '575 specification. *Compare In re Wertheim*, 541 F.2d 257, 265 (C.C.P.A. 1976) (finding sufficient written description for the claim term 35-60% where the specification recites a range of 25-60% along with specific embodiments of 36% and 50%).

Accordingly, we find that the limitation "about 6.6. x 10^{11} particles per ml" is not sufficiently supported by a written description under 35 U.S.C. § 112, first paragraph, in GHC's specification.

C.

We also consider Sienna's arguments regarding the lack of written description for GHC's claim phrase "unassembled plasmonic nanoparticle." (*See* Sienna Motion 1, Paper 84, at 4:25-14:23.)

The parties agree that the specification of GHC's involved '575 application does not expressly recite the phrase "unassembled plasmonic nanoparticle" or the term "unassembled." (Sienna Motion 1, Paper 84, at 4:28-29; GHC Opp. 1, Paper 222, at 9:9-10.) Sienna argues that the absence of this term indicates a lack

of express written description support. Sienna argues further that there is no inherent support for the phrase in GHC's specification. (Sienna Motion 1, Paper 84, at 2:1-13.)

To determine if GHC's specification would convey possession of a method using a composition of "unassembled plasmonic nanoparticles," we first look to the meaning of that phrase in GHC's claims.

Sienna argues that GHC copied the phrase from Sienna's claims. (Sienna Motion 1, Paper 84, at 4:30-5:1.) The phrase did not appear in GHC's claims until GHC filed claims 65-67 (and other claims), which GHC ultimately relied upon to suggest this interference. (*See* Sienna Motion 1, Paper 84, at 4:29-5:1, citing Supplemental Amendment and Response to Non-Final Office Action, Exh. 1027, at 6-8; *see also* Suggestion for Declariaton of Interference in GHC's '575 appl.) GHC does not dispute that it copied this phrase from Sienna's claims.

Because the phrase was copied, we look to Sienna's specification for its meaning. *See Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1375 (Fed. Cir. 2009) ("[W]hen a party challenges written description support for an interference count or the copied claim in an interference, the originating disclosure provides the meaning of the pertinent claim language."). (*See* Sienna Motion 1, Paper 84, at 5:9-11.) Sienna's specification provides the following discussion:

> Assembly.
>
> The nanoparticles provided herein can generally contain a collection of unassembled nanoparticles. By "*unassembled*" nanoparticles it is meant that nanoparticles in such a collection are not bound to each other through a physical force or chemical bond either directly (particle-particle) or indirectly through some intermediary

> (e.g. particle-cell-particle, particle-protein-particle, particle-analyte-particle). In other embodiments, the nanoparticle compositions are *assembled* into ordered arrays. In particular, such ordered arrays can include any three dimensional array. . . . The nanoparticles are assembled by a van der Walls attraction, a London force, a hydrogen bond, a dipole-dipole interaction, or a covalent bond, or a combination thereof.

('941 Spec., Exh. 1004, at 9:39-56 (emphasis added).) According to this passage, Sienna's specification defines "unassembled" nanoparticles as those not bound to each other by physical forces or chemical bonds (either directly or indirectly through an intermediary). This state is contrasted with nanoparticles that are "assembled." Assembled nanoparticles are those that are arranged in ordered arrays due to van der Waals or London forces, hydrogen bonds, a dipole-dipole interaction, or a covalent bond. Sienna must prove that GHC's claims do not describe nanoparticles with no association by physical forces or chemical bonds.

Sienna argues that paragraphs 13 and 79 of the GHC specification do not provide a written description of "unassembled plasmonic nanoparticles." (Sienna Motion 1, Paper 84, at 5:24-14:23.) Sienna notes that GHC cited to paragraphs 13 and 79 as support for this claim phrase when it requested an interference. (*See* GHC 202 Statement, Exh. 1011, App'x D at 1.)

Paragraph 13 recites:

> the invention provides a composition comprising a cosmetically acceptable carrier and a plurality of plasmonic nanoparticles in an amount effective to induce thermomodulation in a target tissue region with which the composition is topically contacted.

(GHC '575 appl., Exh. 1024, at ¶ 13.) Paragraph 79 of the GHC specification states:

> In another embodiment, nanoshells used are composed of a 120 nm diameter silica core with a 15 [nm][10] thick gold shell, giving a total diameter of 150 nm. The nanoshell is covered by a 5,000 MW PEG [polyethylene glycol] layer. The PEG layer prevents and/or reduces nanoshell aggregation, thereby increasing the nanoshell suspensions stability and shelf-life.

('575 appl., Exh. 1024, ¶ 79.)

Neither paragraph 13 nor paragraph 79 of GHC's specification uses the term "unassembled" when referring to nanoparticles. Neither paragraph refers to any physical forces or chemical bonds that would cause nanoparticles to assemble. Paragraph 79 only expresses that the nanoparticles are not "aggregated" due to a PEG layer.

Sienna argues that those of skill in the art would have understood that "non-aggregated" nanoparticles are not the equivalent of "unassembled" nanoparticles because nanoparticles may be non-aggregated without being unassembled. (Sienna Motion 1, Paper 84, at 6:8-12.) Sienna relies on the testimony of Dr. Tao in support. Dr. Tao testifies that those of skill in the art would have understood aggregated nanoparticles to be the result of forces such as van der Waals or

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[10] Although the text provides for a "15 micron thick gold shell," it is reasonable that this measurement should have been 15 nm. (*See* Second Declaration of Ivan J. Dmochowski, Exh. 2025, at ¶ 146, FN 35; *see also* Deposition of Andrea Tao, Ph.D., Exh. 2114, at 56:3-57:14.)

London forces only, while assembly is the result of these forces or also dipole-dipole interactions, hydrogen bonds, or chemical bonds. (*See* Tao Decl., Exh. 1002, at ¶¶ 54-59.) The evidence that Dr. Tao cites is not persuasive. For example, Dr. Tao cites to Min[11] to show that the scientific literature refers to "aggregation" as the clustering of nanoparticles caused by physical adhesion forces like the van der Waals attraction or London force (Tao Decl., Exh. 1002, at ¶ 60), but Min does not discuss the forces to which *non*-aggregated nanoparticles are subject. Dr. Tao also provides diagrams and tables to distinguish between "non-aggregated" and "unassembled" nanoparticles (*see* Tao Decl., Exh. 1002, at ¶¶ 57 and 59), but this testimony is not supported by references to show that those of skill in the art would have had the same understanding. Thus, Dr. Tao's testimony does not help us to understand anything about the nanoparticles of GHC's paragraph 79. Her testimony does not persuade us about the state of assembly of the nanoparticles of GHC's paragraph 79.

Sienna assumes that if the GHC specification does not use the exact language of its claims, support can only be inherent. But the written description requirement does not demand recitation of a claimed invention *in haec verba. Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010). Instead, "the failure of the specification to specifically mention a limitation that later appears in the claims is not a fatal one when one skilled in the art would

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[11] Min et al., "The role of interparticle and external forces in nanoparticle assembly," 7 NATURE MATERIALS 527 (2008)

recognize upon reading the specification that the new language reflects what the specification shows has been invented." A*ll Dental Prodx, LLC v. Advantage Dental Products, Inc.*, 309 F.3d 774, 779 (Fed. Cir. 2002). In *All Dental Products* the court held that a claim to a method of making a dental mold with the step "heating an original *unidentified* mass of thermosetting material . . ." was sufficiently described because the description in the specification involved heating a thermoplastic mass that did not have an identifiable form or shape. Even though the words "original unidentified mass" were not recited in the specification, the court's holding did not rely on an inherent description because those of skill in the art would have understood the lack of a shape from the description.

Like the facts of *All Dental Products*, GHC's claims recite nanoparticles that lack a structure – assembly. In the absence of evidence that those of skill in the art would know the nanoparticles described in GHC's specification have this structure, we are not persuaded that it does. Sienna's evidence directed towards showing that non-aggregated nanoparticles may be assembled does not persuade us that the nanoparticles of paragraph 79 are assembled. (*See* Tao Decl., Exh. 1002, at ¶¶ 56-69.) Even though the exact term "unassembled" does not appear in GHC's specification, we are not persuaded that the nanoparticles described therein are assembled. Because nanoparticles can be either assembled or unassembled – there being no third choice demonstrated by Sienna – and we have no reason to consider the nanoparticles of paragraph 79 to be assembled, we consider them to be unassembled.

We need not consider Sienna's arguments regarding inherent disclosure of "unassembled plasmonic nanoparticles" in GHC's specification (*see* Sienna Motion 1, Paper 84, at 7:13-14:23) because our determination is not based on an inherent disclosure. Sienna does not give us any reason to find that those of skill in the art would consider the nanoparticles of the GHC specification to be assembled from the express language of the specification.

Accordingly, Sienna fails to meet its burden of showing that the limitation "unassembled plasmonic nanoparticles" in GHC's claims lacks sufficient written description under 35 U.S.C. § 112, first paragraph in GHC's '575 application.

D.

Even though Sienna has failed to persuade us that GHc's claim term "unassembled plasmonic nanoparticles" lacks written description support, because we find that the term "about 6.6 x 10^{11} nanoparticles per ml" is not described we hold that claims 65-67 are unpatentable under 35 U.S.C. § 112, first paragraph.

III. GHC Contingent Motion 4 – To add claim 74

A.

GHC requests that new claim 74 be added to its involved '575 application. GHC's proposed claim 74 is reproduced below, with strikethough font to indicate deleted text and underlining to indicate added text compared to GHC's currently pending claim 65:

> A method of localizing thermal damage to a hair follicle, comprising:
> applying a composition to a skin surface,

wherein said composition comprises a plurality of unassembled plasmonic nanoparticles,

wherein the unassembled plasmonic nanoparticles comprise a conductive metal portion,

wherein the conductive metal portion comprises gold,

wherein the unassembled plasmonic nanoparticles have a diameter of about 150 nm,

wherein the unassembled plasmonic nanoparticles comprise a coating that coats the conductive metal portion, wherein said coating facilitates selective removal from the skin surface,

wherein the coating comprises polyethylene glycol (PEG),

wherein the composition comprising unassembled plasmonic nanoparticles has ~~have a concentration~~ an Optical Density of 250 O.D. when measured at a wavelength of about 810 nm ~~of about 6.6 x 10^{11} particles per ml of the composition~~, wherein said composition ~~concentration~~ is sufficient to, after exposure to irradiation, induce thermal damage in the hair follicle;

distributing the composition from the skin surface to the hair follicle to target the hair follicle;

selectively removing the composition from the skin surface, while leaving the composition localized within the hair follicle; and

irradiating the composition with an infrared light source thereby inducing a plurality of surface plasmons in said unassembled plasmonic nanoparticles, wherein the induction of the surface plasmons generates thermal damage to the hair follicle for at least one of hair removal or hair growth reduction.

(GHC Motion 4, Paper 162, at Appd'x 3A.) Proposed claim 74 deletes the limitation "wherein the unassembled plasmonic nanoparticles have a concentration of about 6.6 x 10^{11} particles per ml" and replaces it with the limitation "wherein the composition comprising unassembled plasmonic nanoparticles has an Optical Density of 250 O.D. when measured at a wavelengthof about 810 nm." (*See* GHC Motion 4, Paper 162, at 5:25-6:1.)

B.

GHC fails to meet the burden it undertook in seeking to add a new claim to the interference. *See* 37 C.F.R. § 41.121(b)("The party filing the motion has the burden of proof to establish that it is entitled to the requested relief.") When moving to add a claim to an application and the interference, the movant must, among other things, certify that the proposed claim is patentable, show why there would still be an interference-in-fact between the proposed claim and the opponent's involved claims, and show that the proposed claim corresponds to a count in the interference. (*See* Standing Order ¶ 208.5.1.)

GHC implies it does not have to meet this burden on some issues because the declaration of this interference is an interlocutory finding. (*See, e.g.,* GHC Reply 4, Paper 246, at 2:25-27; 3:24-26; 5:3-7; and 6:15-18.) Similarly, GHC argues that claim 74 must be patentable because GHC was allowed to file Motion 4 proposing it. (GHC Reply 4, Paper 246, 1:15-18.) GHC is wrong. A declaration of interference is a rebuttable determination that, in the opinion of the Director, as delegated to an administrative patent judge, claims of a pending application interfere with claims of another application or unexpired patent. (*See* 35 U.S.C. § 135(a); *see also* 37 C.F.R. § 41.203.) Declaration of an interference is not a legal conclusion or finding of fact regarding any issue for which a party assumes the burden. Thus, the declaration of this interference is not a determination of the patentability of proposed claim 74 or of any relationship between GHC's proposed claim 74 and Sienna's claims or Count 1.

GHC argues that proposed claim 74 interferes with the claims of Sienna's

'941 patent because none of the differences between the claims "creates a patentable distinction." (GHC Motion 4, paper 162, at 6:22-25.) GHC does a cursory comparison between the claims, noting that proposed claim 74 presents several limitations within the scope of ranges recited in Sienna's claims. For example, GHC notes that Sienna's claim 1 recites nanoparticles having a size in the range of 10 nm to 300 nm and GHC's proposed claim 74 recites nanoparticles having a diameter of about 150 nm. (GHC Motion 4, Paper 162, at 8:12-14.) Similarly, GHC notes that Sienna's claim 1 recites a "concentration of 10^9 to 10^{23} nanoparticles per ml of the composition" while GHC's proposed claim 74 recites "an Optical Density of 250 O.D. when measured at a wavelength of about 810 nm." (GHC Motion 4, Paper 162, at 8:18-21.) GHC argues that for each of these limitations, proposed claim 74 recites "a single member of a class" or a "species" of the scope of the limitation in Sienna's claim. (GHC Motion 4, Paper 162, at 8:5-9.)

"An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa." 37 C.F.R. § 41.203(a). "A claim corresponds to a count if the subject matter of the count, treated as prior art to the claim, would have anticipated or rendered obvious the subject matter of the claim." 37 C.F.R. § 41.207(b)(2). Count 1 in this interference is Sienna '941 patent claim 1. Thus, to show interference-in-fact with Sienna claim 1 or correspondence to Count 1, GHC must show that proposed claim 74 is anticipated or rendered obvious by Sienna claim 1. GHC fails to do so.

GHC's argument that the limtiations of proposed claim 74 "fall within" the limitations of Sienna claim 1 does not show whether GHC's narrower limitations would have been obvious over the broader limitations. "It is well established that the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus. . . . . There may be many species encompassed within a genus that are not disclosed by a mere disclosure of the genus." *Atofina v. Great Lakes Chem. Corp.,* 441 F.3d 991, 999 (Fed. Cir. 2006) (citations omitted). Furthermore, "[a] disclosure of millions of compounds does not render obvious a claim to three compounds, particularly when that disclosure indicates a preference leading away from the claimed compounds." *In re Baird*, 16 F.3d 380, 383 (Fed. Cir. 1994). GHC does not direct us to evidence showing that one of skill in the art would have considered it obvious to have chosen the narrow range of nanoparticle diameter and optical density recited in its proposed claim 74, given the wide ranges recited in Sienna's claim 1.[12] Accordingly, GHC has failed to meet its burden of showing that proposed claim 74 interferes with any of Sienna's claims. For the same reasons, GHC also fails to meet its burden to show that proposed claim 74 would correspond to Count 1.

Furthermore, GHC "certifies" that it is not aware of any reason why claim 74 is not patentable (GHC Motion 4, paper 162, at 4:2-3), but fails to direct

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[12] GHC's arguments that a composition as recited in proposed claim 74 would work to induce thermal damage in a hair follicle do not address whether Sienna's claim would render obvious proposed claim 74. (*See* GHC Motion 4, Paper 162, at 9:1-9.)

us to supporting evidence, such as the testimony of a skilled artisan qualified to opine on the relevant prior art.

C.

Because GHC fails to meet its burden to show that proposed claim 74 is patentable, interferes with any of Sienna's involved claims, or corresponds to Count 1, we deny GHC Responsive Motion 4.

III. Conclusion

A.

We grant Sienna Motion 1, finding that GHC's claims 65-67 are unpatentable under 35 U.S.C. § 112, first paragraph.

We deny GHC Responsive Motion 4, denying GHC's request to add proposed claim 74 to its involved '575 application.

We deny, in part, GHC Motion 8 to exclude evidence relied upon in our decision. We dismiss as moot GHC's arguments regarding evidence we do not rely upon.

Because we would grant Sienna Motion 1 and deny GHC Motion 4 even if we do not exclude the evidence cited by Sienna in its Motion to Exclude, we dismiss that motion as moot.

B.

Sienna's Motion 1, challenging the written description support for GHC's involved claims, presents the issue of whether GHC has standing in this interference. *See* 37 C.F.R. § 41.201.

Applicant GHC suggested this interference in a statement filed 15 July 2015 under 37 C.F.R. § 202(d). The suggestion cited GHC's '575 application claims filed 1 January 2015 and Sienna's '941 patent claims issued on 2 September 2014. Thus, GHC suggested the interference based on claims that were filed after the issue of Sienna's patent claims. Because GHC's interfering claims are not sufficiently supported by its specification, it has no basis on which to challenge the patentability of Sienna's claims under 35 U.S.C. § 102(g) or any other part of the statute. GHC does not argue to the contrary. As discussed above, in addition to granting Sienna Motion 1, we deny GHC Responsive Motion 4 to add a claim to the interference. Thus, GHC has no claims remaining.

Accordingly, Sienna's remaining motion is moot and we do not consider GHC's motions challenging Sienna's involved claims. *Cf. Berman v. Housey*, 291 F.3d 1345, 1351 (Fed. Cir. 2002) ("Accordingly, we hold that § 135(b) is a threshold issue that should be addressed by the Board at the preliminary stage of an interference before proceeding to the merits, and that the Board in this case properly refused to consider Berman's unpatentability motion once it determined that Berman's claim 64 was barred under § 135(b).").

We enter judgment against GHC separately, finally refusing its involved claims and terminating the interference.

cc (via e-mail):

Attorney for Junior Party General Hospital:

Peter C. Lauro
Brian R. Landry
SAUL EWING LLP
plauro@saul.com
blandry@saul.com

Philippe Bennett
Walter Scott
ALSTON & BIRD, LLP
philippe.bennett@alston.com
scott@alston.com

Attorney for Senior Party Sienna:

Brenton R. Babcock
Salima A. Merani
Ted M. Cannon
KNOBBE, MARTENS, OLSON & BEAR, LLP
BoxSienna@knobbe.com

Michael R. Fleming
IRELL & MANELLA LLP
MFleming@irell.com