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Paper 8
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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COALITION FOR AFFORDABLE DRUGS II LLC,
Petitioner,

v.

COSMO TECHNOLOGIES LTD.,
Patent Owner.

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Case IPR2015-00988
Patent 6,773,720 B1

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Before JACQUELINE WRIGHT BONILLA, SHERIDAN K. SNEDDEN, and SUSAN L. C. MITCHELL, *Administrative Patent Judges.*

BONILLA, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
*37 C.F.R. § 42.108*

## I. INTRODUCTION

Coalition For Affordable Drugs II LLC ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–4 of U.S. Patent No. 6,773,720 B1 (Ex. 1001, "the '720 patent"). Paper 1 ("Petition" or "Pet."). Cosmo Technologies Ltd. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 7 ("Prelim. Resp."). We have statutory authority under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

Petitioner challenges claims 1–4 of the '720 patent as unpatentable under 35 U.S.C. § 103(a). Pet. 13–14, 19–60. Based on the information presented in the Petition and Preliminary Response, we are persuaded there is a reasonable likelihood Petitioner would prevail with respect to the claims challenged in the Petition. Thus, we institute *inter partes* review of claims 1–4 of the '720 patent.

### *A. Related Proceedings*

The parties identify the following as related district court proceedings regarding the '720 patent: *Shire Development LLC v. Mylan Pharms., Inc.*, FLMD-8-12-cv-01190 (M.D. Fla.) (filed May 25, 2012); *Shire Development LLC v. Watson Pharms., Inc.*, FLSD-0-12-60862 (S.D. Fla.) (filed May 8, 2012); *Shire Development LLC v. Osmotical Pharm. Corp.*, GAND-1-12-cv-00904 (N.D. Ga.) (filed March 16, 2012); *Shire Development LLC v. Cadila Healthcare Ltd.*, DED-1-10-cv-00581 (D. Del.) (filed July 7, 2010). Pet. 2–3; Paper 5, 2.

*B. Proposed Grounds of Unpatentability*

Petitioner advances three grounds of unpatentability under 35 U.S.C. § 103(a) in relation to all challenged claims in the '720 patent (Pet. 13–14):

| **Reference[s]** | **Statutory Basis** | **Challenged Claims** |
|---|---|---|
| Leslie (Ex. 1003)[1] | § 103(a) | 1–4 |
| Leslie (Ex. 1003) and Rhodes (Ex. 1004)[2] | § 103(a) | 1–4 |
| Groenendaal (Ex. 1005)[3] and Leslie (Ex. 1003) | § 103(a) | 1–4 |

In addition, Petitioner supports its challenges in the Petition with a Declaration by Anthony Palmieri III, Ph.D. ("Palmieri Decl.") (Ex. 1037).

*C. The '720 Patent*

The '720 patent is directed to controlled release oral pharmaceutical compositions containing 5-amino salicylic acid, also known as mesalazine or 5-ASA, as an active ingredient. Ex. 1001, 1:4–6. Mesalazine is used to treat Crohn's disease and ulcerative colitis, which involve inflammation of the intestines. *Id*. at 1:9–11. The compositions comprise (1) "an inner lipophilic matrix consisting of substances with [a] melting point below 90° C. in which the active ingredient is at least partially inglobated," and (2) "an outer hydrophilic matrix in which the lipophilic matrix is dispersed." *Id*. at 2:36–44. The specification describes that "[p]art of mesalazine can optionally be

[1] Leslie, U.S. Patent No. 3,965,256, filed June 5, 1974, issued June 22, 1976 ("Leslie") (Ex. 1003).
[2] Rhodes et al., U.S. Patent No. 5,541,170, filed Mar. 10, 1995, issued July 30, 1996 ("Rhodes") (Ex. 1004).
[3] Groenendaal et al., EP Appl. Publ. No. 0 375 063 A1, filed Dec. 18, 1989, published on June 27, 1990 ("Groenendaal") (Ex. 1005).

mixed with hydrophilic substances to provide compositions in which the active ingredient is dispersed both in the lipophilic and the hydrophilic matrix." *Id*. at 3:34–39.

The specification states that the "lipophilic matrix consists of substances selected from unsaturated and/or hydrogenated fatty acids, salts, esters or amides thereof, fatty acids mono-, di- or triglycerids, waxes, ceramides, cholesterol derivatives or mixtures thereof having melting point within the range of 40 to 90° C." *Id*. at 3:1–5. In addition, the hydrophilic matrix "consists of excipients known as hydrogels," which include "compounds selected from polymers or copolymers of acrylic or methacrylic acid, alkylvinyl polymers, hydroxyalkyl celluloses, carboxyalkyl celluloses, polysaccharides, dextrins, pectins, starches and derivatives, natural or synthetic gums, alginic acid." *Id*. at 3:18–30.

*D. Claims*

The '720 patent contains four claims. Independent claim 1 and dependent claim 4 are reproduced in their entirety below.

> 1. Controlled-release oral pharmaceutical compositions containing as an active ingredient 5-amino-salicylic acid, comprising:
>
> a) an inner lipophilic matrix consisting of substances selected from the group consisting of unsaturated and/or hydrogenated fatty acid, salts, esters or amides thereof, fatty acid mono-, di- or triglycerids, waxes, ceramides, and cholesterol derivatives with melting points below 90º C., and wherein the active ingredient is dispersed both in said the lipophilic matrix and in the hydrophilic matrix;
>
> b) an outer hydrophilic matrix wherein the lipophilic matrix is dispersed, and said outer hydrophilic matrix consists of compounds selected from the group consisting of polymers or copolymers of acrylic or methacrylic acid, alkylvinyl

> polymers, hydroxyalkyl celluloses, carboxyalkyl celluloses, polysaccharides, dextrins, pectins, starches and derivatives, alginic acid, and natural or synthetic gums;
>
> c) optionally other excipients;
>
> wherein the active ingredient is present in an amount of 80 to 95% by weight of the total composition, and wherein the active ingredient is dispersed both in the lipophilic matrix and in the hydrophilic matrix.
>
> 4. A process for the preparation of the compositions of claim 1, which comprises:
>
> a) melt granulation of at least one portion of the active ingredient with the lipophilic excipients with melting point lower than 90º C.;
>
> b) mixing the granules from step a) with the hydrophilic excipients and subsequent tabletting or compression.

Claim 2 depends from claim 1, and recites the "5-aminosalicylic acid is dispersed in a molten lipophilic matrix by kneading, extrusion and/or granulation." Claim 3, which also depends from claim 1, recites that the composition is "in the form of tablets, capsules, mintablets."

## II. ANALYSIS

### *A. Real Parties-in-Interest*

Patent Owner asserts that the Petition incorrectly identifies listed entities (Pet. 1–2) as the only real parties-in-interest. Prelim. Resp. 33–41. Patent Owner argues that to comply with statutory requirements under 35 U.S.C. § 312(a)(2), the Petition also should have identified (1) all sister "Coalition for Affordable Drugs" or "CFAD" entities, and (2) all individuals or entities who have invested in the listed real parties-in-interest. *Id*.

*1. Sister "CFAD" entities*

In relation to the "sister" companies of Petitioner, i.e., Coalition for Affordable Drugs (ADROCA) LLC and Coalition for Affordable Drugs III–XV (Ex. 2014), Patent Owner contends that "[d]ue to the significant corporate blurring between these virtually identical entities, these CFAD sister companies all appear to have an opportunity to control the present proceedings." Prelim. Resp. 34–35. Patent Owner contends that "[e]ach entity was formed by the same person (Christopher E. Kirkpatrick), each entity has the same registered office address (c/o Capitol Service, Inc. in Dover, DE), and each entity that has filed an IPR is a wholly-owned subsidiary of the same entity (Hayman Credes Master Fund, L.P)." *Id*. at 37–38 (citing Ex. 2014).

A patent owner challenging a petitioner's RPI disclosure must provide sufficient evidence to show the disclosure is inadequate. *Intellectual Ventures Mgmt., LLC v. Xilinx, Inc.*, Case IPR2012-00018, slip op. at 3–4 (PTAB Jan. 24, 2013) (Paper 12). When a patent owner provides sufficient evidence prior to institution that reasonably brings into question the accuracy of a petitioner's identification of real parties-in-interest, the ultimate burden remains with the petitioner to establish that it has complied with the statutory requirement to identify all real parties-in-interest. *Zerto, Inc. v. EMC Corp.*, Case IPR2014-01254, slip op. at 6–7 (PTAB Feb. 12, 2015) (Paper 32).

As Patent Owner asserts, evidence before us indicates that corporate "blurring" exists between the different CFAD sister entities. That factor weighs in favor of finding the sister entities to be real parties-in-interest. *Zoll Lifecor Corp. v. Philips Elec. N. Am. Corp.*, Case IPR2013-00606, slip

op. at 10 (PTAB Mar. 20, 2014) (Paper 13); *Galderma S.A. v. Allergan Industrie, SAS*, Case IPR2014-01422, slip op. at 12 (PTAB Mar. 5, 2015) (Paper 14). As Patent Owner also notes, however, we consider multiple factors when assessing whether a non-party is a real party-in-interest ("RPI") in a given proceeding. Prelim. Resp. 35–36.

As stated in our Trial Practice Guide, the RPI inquiry "is a highly fact-dependent question"—there is no "bright line test." 77 Fed. Reg. 48,756, 48,759 (Aug. 14, 2012) (Trial Practice Guide). Although "rarely will one fact, standing alone, be determinative of the inquiry" (*id*. at 48,760), "[a] common consideration is whether the non-party exercised or could have exercised control over a party's participation in a proceeding." *Id*. at 48,759 (citations omitted)); *Reflectix, Inc. v. Promethean Insulation Tech. LLC*, Case IPR2015-00039, slip op. at 12 (PTAB April 24, 2015) (Paper 18). Along those lines, the RPI requirement exists to ensure that a non-party is not "litigating through a proxy." *Aruze Gaming Macau, Ltd. v. MGT Gaming, Inc.*, Case IPR2014-01288, slip op. at 12 (PTAB Feb. 20, 2015) (Paper 13). Thus, when assessing RPI, we inquire into the "relationship between a party and a *proceeding*," and consider "the degree of control the nonparty could exert over the *inter partes* review, not the petitioner." *Id*. at 11.

Additional considerations may include whether a non-party "funds and directs and controls" an IPR petition or proceeding; the non-party's relationship with the petitioner; the non-party's relationship to the petition itself, including the nature and/or degree of involvement in the filing; and the nature of the entity filing the petition. Trial Practice Guide, 77 Fed. Reg.

at 48,760. A party does not become a RPI merely through association with another party in an endeavor unrelated to the AIA proceeding. *Id.*

Here, the CFAD sister entities are petitioners in other cases before the Board involving different patent owners and challenged patents. Even assuming significant overlap or blurring in terms of corporate structure between the sister entities, Patent Owner does not point us to evidence explaining or establishing sufficiently the relationship of the sister entities (or corporate officers, employees, or counsel acting on their behalf) to this proceeding in particular.

In addition, the record before us does not indicate sufficiently that any sister entity, acting in its own capacity, has or could have exerted control over this case, rather than other case(s) where the sister entity is a petitioner. Evidence does not indicate sufficiently we are dealing with a situation where a non-party, i.e., one or more sister entities, is "litigating through a proxy," i.e., Petitioner here. *Aruze*, Case IPR2014-01288, slip op. at 12 (PTAB Feb. 20, 2015) (Paper 13).

Likewise, insufficient evidence exists to indicate that a sister entity funded or otherwise paid for expenses associated with the Petition, or that a sister entity in its own capacity (or via its legal counsel) controlled or participated in the filing of the Petition in this case. For example, insufficient evidence exists to indicate that a sister entity, in its own right, provided support services, such as legal services, to Petitioner here. *See Par Pharms. Inc. v. Jazz Pharms., Inc.*, Case IPR2015-00548, slip op. at 15–18 (PTAB July 28, 2015) (Paper 19) (discussing *Zoll*, Case IPR2013-00606, slip op. at 10 (PTAB Mar. 20, 2014) (Paper 13)), *Atlanta Gas Light Co. v. Bennett Regulator Guards, Inc.*, Case IPR2013-00453, slip op. at 2–3, 9

(PTAB Jan. 6, 2015) (Paper 88), *Zerto*, Case IPR2014-01254, slip op. at 13 (Paper 32)).

As noted above, when assessing RPI, rarely does one factor control. Here, evidence points to blurring among the sister entities in terms of corporate structure, but insufficient evidence exists in relation to other relevant factors, such as whether a sister entity has controlled, or had the ability to control, the filing of the Petition in this case. Based on the particular facts of this case, in view of the evidence before us, we are not persuaded that Patent Owner has provided sufficient evidence to show that Petitioner's disclosure of real parties-in-interest is inadequate in relation to the CFAD sister entities.

*2. Investors*

Patent Owner also contends that Petition fails to identify individuals or entities who have invested in the RPIs listed in the Petition. Prelim. Resp. 39–41. Patent Owner points to where our Trial Practice Guide states: "[A]t a general level, the 'real party-in-interest' is the party that *desires review* of the patent." *Id*. at 39 (quoting Trial Practice Guide, 77 Fed. Reg. at 48,759 (emphasis added)). As discussed above, however, we consider multiple factors when assessing whether a party is a RPI who desires review.

The record before us does not persuade us sufficiently that any individual or entity who has invested in the listed RPIs has or could have exerted control over the filing of the Petition in this case. Likewise, insufficient evidence exists as to whether any unnamed investor funded or otherwise paid for expenses associated with the Petition, or if an unnamed investor in its own capacity (or via its legal counsel) controlled or participated in the filing of the Petition here. The record presents little to no

information as to how any unnamed investor relates to, or could have participated in, this proceeding in particular.

Based on the particular facts of this case, in view of the evidence before us, we are not persuaded that Patent Owner has provided sufficient evidence to show that Petitioner's disclosure of real parties-in-interest is inadequate in relation to individuals or entities who have invested in the listed real parties-in-interest.

*B. Claim construction*

For *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the patent specification. 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015). Claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner provides proposed constructions of certain terms in the challenged claims. Pet. 10–13. For example, Petitioner argues that "matrix" means "a macroscopically homogeneous structure in all its volume." Pet. 10 (citing Ex. 1001, 3:42–45). Petitioner also addresses "consisting of substances selected from the group consisting of" and "consists of compounds selected from the group consisting of" in claim 1, as relating to the recited inner lipophilic matrix and outer hydrophilic matrix, respectively. *Id*. at 12–13. Petitioner contends that "[a]lthough 'substances' and

'compounds' are written in the plural form, the broadest reasonable interpretation of the terms also includes the singular form where, as here, the plural merely refers to a group of objects." *Id*. at 12.

Patent Owner does not challenge Petitioner's proposed constructions, nor propose alternative constructions for any claim term. *See, e.g.*, Prelim. Resp. 18–19 (discussing, but not disagreeing with, Petitioner's proposed claim construction of "matrix"). For the purposes of institution, we adopt the proposed claim constructions asserted by Petitioner regarding various terms mentioned above as the broadest reasonable interpretation of those terms in view of the specification at issue.

*C. Asserted Obviousness of claims 1–4 over Groenendaal (Ex. 1005) and Leslie (Ex. 1003)*

Petitioner contends that claims 1–4 of the '720 patent would have been obvious over Groenendaal in view of Leslie. Pet. 48–60. Petitioner contends that "[o]ne of ordinary skill in the art would have been motivated to combine the formulations taught in Leslie with the high-dose of 5-ASA from Groenendaal with a reasonable expectation of success in formulating the composition disclosed in the Claims." *Id*. at 48–49.

*1. Leslie*

Leslie discloses slow release oral compositions comprising a combination of a higher aliphatic alcohol and a hydrated hydroxy-alkyl cellulose. Ex. 1003, 1:8–21. That combination "in critical proportions of one to the other . . . delays the release of a therapeutically active compound." *Id*. at 3:37–51. Regarding the higher aliphatic alcohol, Leslie states that "a particularly preferred alcohol is cetyl alcohol." *Id*. at 4:54–62. Leslie further discloses that "it is important that the alkyl cellulose component be

hydrated," and the "hydroxy-alkyl cellulose preferred in practice is hydroxyethyl cellulose." *Id*. at 4:30–53.

Leslie teaches that the "active therapeutic compound intended for therapy may be incorporated in the higher alcohol before this is blended with the hydrated hydroxy-alkyl cellulose, or it may be incorporated in the hydrated hydroxy-alkyl cellulose, before it is incorporated with the higher alcohol or divided among both agents." *Id*. at 4:63–68. Leslie further teaches that "[b]oth the pharmacologic nature of the active therapeutic ingredient and the dosage to be incorporated into the present sustained slow release composition, are not critical to the present invention," and that "[e]xamples of such pharmacologically active ingredients" include "salicylate and acetyl-salicylate compounds." *Id*. at 8:37–59; 13:62–67.

Leslie presents example formulations and methods for making the described compositions. Example 1 presents a general method for making such compositions. *Id*. at 10:30–68. Example 1 discloses hydrating hydroxy ethyl cellulose, melting cetyl alcohol and adding it to a diluent, such as lactose or talc, which is granulated. *Id*. at 10:30–38. "The granules of cetyl alcohol are added to the hydrated hydroxy ethyl cellulose" and the "whole is then well blended and to it is added the selected active ingredient as well as further diluents . . . to permit compression into tablets." *Id*. at 10:39–48.

In Example 4, Leslie discloses (1) melting cetyl alcohol at 60º–70ºC and incorporating it with aminophylline, an active ingredient, by stirring, (2) hydrating hydroxy ethyl cellulose, (3) incorporating the blend from (1) with a "[t]otal blending time [of] three hours," and (4) drying "the resultant granular mass," and passing it through a mesh sieve before making tablets. *Id*. at 12:21–47. The composition comprises "73.00 % w/w" of the active

ingredient aminophylline. *Id*. at 12:23–26. Example 6 in Leslie discloses a similar composition and manufacturing process, but includes 75 g of the active ingredient papaverine hydrochloride (out of 100 g total for the composition), i.e., 75% by weight of the total composition. *Id*. at 13:19–40.

Example 5 in Leslie discloses (1) hydrating hydroxy ethyl cellulose, (2) adding potassium chloride as an active ingredient to the hydrated cellulose "with constant stirring" "until a free-flowing uniform granule blend is obtained," (3) drying and granulating the cellulose-potassium chloride granules; (4) melting cetyl alcohol at 50º–60ºC, and incorporating the granules from (3), with "[c]ontinue[d] stirring until a free-flowing granular mass is obtained" before lubricating the granules and pressing them into "cores." *Id*. at 12:48–13:15. The composition includes 82 g of potassium chloride (out of 102 g total for the composition), i.e., the active ingredient is 80% by weight of the total composition. *Id*. at 12:51–54.

Example 7 in Leslie states that when one desires to "incorporate a pharmacologically active compound with the slow release composition of Example 1 above, then said active agent may be added to the alcohol component or the cellulose component or divided between the two." *Id*. at 13:43–47.

*2. Groenendaal*

Groenendaal discloses "controlled-release oral compositions comprising biologically active substances, targeted to predetermined parts of the intestine and especially to the lower part thereof." Ex. 1005, 2:1–3. The compositions are in the form of a "solid dispersion," which the reference defines "as a dispersion of one or more active ingredients in an inert

excipient at solid state prepared by the melting (fusion), solvent, or melting-solvent method." *Id*. at 2:14–18.

Groenendaal discloses mixing water-insoluble carrier particles "with the dispersion before it is solidified, without any need to actively deposit the solid on the carrier cores." *Id*. at 2:49–50. More specifically, Groenendaal teaches

> a method for preparing a granulate for a multiparticulate oral composition based on the concept of solid dispersion, whereby a biologically active substance is dispersed in an acid-resistant or release-limiting substance using the melting, the solvent or the melting-solvent method, characterized in that before the dispersion is solidified it is mixed with water-insoluble carrier particles whereafter the complete mixture is further processed according to granulation methods known in the art.

*Id*. at 3:1–6.

In addition, Groenendaal discloses that the "percentage of the biologically active compound (w/w) in the solid dispersion can vary between 0.01–99%," but teaches, in particular, that "[w]hen the biologically active compound is a non-steroidal anti-inflammatory compound such as 5- or 4-amino-salicylic acid its percentage (w/w) in the solid dispersion is preferably 20–90%, more preferably 50–80%." *Id*. at 3:31–36.

In Example 5, Groenendaal discloses a sustained release formulation of granules prepared from a mixture comprising 75 g ethylcellulose, 75 g hydrogenated castor oil, 1175 g methylene chloride, 500 g 5-amino salicylic acid (5-ASA), and 450 g water-insoluble carrier powdered cellulose, therefore comprising 22% 5-ASA (500 g 5-ASA out of 2275 g total weight of the composition). *Id*. at 6:1–9. Groenendaal states that Figure 3 shows

that those granules demonstrate sustained release of 5-ASA. *Id*. at 6:16, Fig. 3.

*3. Analysis*

Petitioner contends that that both Leslie and Groenendaal teach controlled release oral pharmaceutical compositions comprising a lipophilic matrix, i.e., a wax (e.g., cetyl alcohol), with a melting point below 90° C, as recited in the challenged claims. Pet. 52–54. In support, Petitioner provides evidence that cetyl alcohol, a higher aliphatic alcohol disclosed in both references, is a wax, and therefore qualifies as a lipophilic matrix, as recited in claim 1. Pet. 21–22 (citing Ex. 1032, 99, 102; Ex. 1031, 5:49–60).

Petitioner further contends that Leslie's composition comprises an inner lipophilic matrix, i.e., granules of cetyl alcohol, dispersed within an outer hydrophilic matrix, i.e., hydroxy-alkyl cellulose or hydroxy ethyl cellulose. Pet. 54–55 (citing Ex. 1003, Examples 4 and 6). Petitioner also points to where Leslie discloses that an "active therapeutic compound . . . may be . . . divided among both agents," i.e., the higher alcohol and the hydrated hydroxy-alkyl cellulose, to show that Leslie teaches that an active ingredient may be dispersed in both the inner lipophilic matrix and the outer hydrophilic matrix, as also recited in claim 1. Pet. 54–55, 57 (citing Ex. 1003, 4:63–68; 13:43–50).

In addition, Petitioner points us to where Groenendaal discloses compositions comprising a "compound such as 5- or 4-amino-salicylic acid," where "its percentage (w/w) in the solid dispersion is preferably 20–90%, more preferably 50–80%." Pet. 49; Ex. 1005, 3:31–36. Petitioner notes that Leslie teaches that its compositions may comprise active ingredients such as "salicylate and acetyl-salicylate compounds," and

contends that "[o]ne of ordinary skill in the art would have recognized that 5-ASA is a species of this preferred API genus." Pet. 20, 51 (citing Ex. 1029, 1298–1301; Ex. 1030, 7:12–16; Ex. 1037 ¶¶ 62–70, 146), 33 (citing Ex. 1003, 8:37–59; 13:62–67). According to Petitioner:

> Because both Groenendaal and Leslie sought the same release control objectives that one of ordinary skill in the art would have been motivated to achieve with respect to 5-ASA, one of ordinary skill in the art would have naturally looked to both Groenendaal and Leslie when seeking to improve 5-ASA formulations.

Pet. 50–51.

Thus, Petitioner contends, one of ordinary skill in the art would have been motivated to use the high percentages of 5-ASA disclosed in Groenendaal in the formulations of Leslie, thereby meeting the limitation of 5-ASA in an "amount of 80 to 95% by weight of the total composition," as recited in claim 1. Pet. 56–57. In further support, Petitioner points to where Leslie discloses a composition in Example 5 comprising potassium chloride in an amount of 80% by weight of the total composition, and where Leslie states "that "[b]oth the pharmacologic nature of the active therapeutic ingredient and the dosage to be incorporated into the present sustained slow release composition, are not critical to the present invention." Pet. 53 (citing Ex. 1003, 8:37–59; 13:62–67).

Consequently, according to Petitioner, one of ordinary skill in the art would have had reason to use the high dose of 5-ASA disclosed Groenendaal in the formulations taught in Leslie, thereby forming the controlled-release composition recited in claim 1 of the '720 patent. Pet. 48–52. In addition, Petitioner contends that Leslie and/or Groenendaal teach

the other limitations recited in challenged dependent claims 2–4. Pet. 57–60.

Based on the record before us, we determine Petitioner has established a reasonable likelihood that it would prevail on its assertion that claims 1–4 of the '720 patent would have been obvious over Groenendaal and Leslie. For the reasons discussed below, Patent Owner does not persuade us otherwise in its Preliminary Response.

First, Patent Owner argues that Leslie does not disclose mesalamine, i.e., 5-ASA, in particular, and that Petitioner fails to establish sufficiently that one of ordinary skill would have had reason to make the compositions of Leslie using 5-ASA. Prelim. Resp. 7–14. Patent Owner also argues that Petitioner fails to establish sufficiently that Leslie, by itself, renders obvious a composition comprising 80–95% active ingredient. *Id*. at 14–18.

On the record before us, Petitioner adequately establishes that Leslie discloses the genus of "salicylate and acetyl-salicylate compounds" as example active ingredients (Ex. 1003, 8:37–59; 13:62–67), which include 5-ASA, as well as examples comprising 73–80% of other active ingredients (Prelim. Resp. 14–15). For the purposes of institution, Petitioner also adequately establishes that one of skill in the art would have combined those teachings in Leslie with Groenendaal's disclosure of 5-ASA at preferably 20–90%, and more preferably 50–80% w/w (Ex. 1005, 3:31–36), to use 5-ASA at the recited concentrations in Leslie's compositions. We are persuaded that Petitioner adequately establishes that one of ordinary skill would have had reason to consider Leslie and Groenendaal together, in view of their overlap in teachings pertaining to controlled release oral

compositions, and disclosures of example active ingredients such as salicylate compounds, including 5-ASA.

Patent Owner also contends that Petitioner fails to show that Leslie discloses a matrix. Prelim. Resp. 18–20. Although Patent Owner does not dispute Petitioner's claim construction of the term "matrix," Patent Owner argues that Petitioner does not show that Leslie discloses any "macroscopically homogeneous structure in all its volume." *Id*. at 18–19.

Petitioner contends, however, that Leslie describes a method for making an inner lipophilic matrix that involves incorporating an active ingredient with cetyl alcohol and "blend[ing] well" before granulating, and making an outer hydrophilic matrix by blending the granules of cetyl alcohol with hydroxy ethyl cellulose and "mix[ing] well." Pet. 54–55 (citing Ex. 1003, 13:19–40, Example 6). On the record before us, we are persuaded that such blending and mixing "well" would have produced, or at least rendered obvious, a "macroscopically homogeneous structure in all its volume," i.e., a matrix as recited the challenged claims. In addition, by providing scientific literature evidence that cetyl alcohol is a wax, Petitioner also sufficiently establishes that Leslie's method produces a lipophilic matrix. Pet. 21–22 (citing Ex. 1032, 99, 102; Ex. 1031, 5:49–60); Prelim. Resp. 21–22 (asserting that Dr. Palmieri's Declaration does not provide sufficient support on its own).

Patent Owner further contends that Groenendaal does not teach a composition where the amount of 5-ASA is 80 to 95% by weight of the total composition. Prelim. Resp. 29–32. Patent Owner contends that Petitioner confuses the "solid dispersion" in Groenendaal with the "total composition" recited in claim 1. Prelim. Resp. 30. Patent Owner contends that the

"compositions in Groenendaal comprise not only a solid dispersion, but also water-insoluble carrier particles and other excipients." *Id*. (citing Ex. 1005, 3:1–6). The passage in Groenendaal cited by Patent Owner in support, however, states that an

> active substance is dispersed in an acid-resistant or release-limiting substance using the melting, the solvent or the melting-solvent method, *characterized in that before the dispersion is solidified it is mixed with water-insoluble carrier particles* whereafter the complete mixture is further processed according to granulation methods known in the art.

Ex. 1005, 3:1–6 (emphasis added). The teaching that "before the dispersion is solidified it is mixed with water-insoluble carrier particles" reasonably indicates that the water-insoluble carrier particles are part of the solid dispersion itself, after the mixture is solidified. *Id*.

Patent Owner also contends that the Petition contains no evidence or analysis relating to secondary considerations. Prelim. Resp. 32–33. The record before us at this stage, however, does not provide adequate evidence of secondary considerations of non-obviousness for us to make a determination that Petitioner fails to establish a reasonable likelihood that it would prevail with respect to at least one claim challenged in the Petition.

*D. Other Grounds*

In addition to the above-mentioned ground, Petitioner further contends that the challenged claims would have been obvious over Leslie and knowledge of a person of ordinary skill in the art (as indicated in certain cited references), or over Leslie in view of Rhodes (Ex. 1004). Pet. 14, 19–48. Limitations and contentions for which Petitioner cites those references, however, are asserted similarly by Petitioner as being met by references cited in the ground discussed above. Given the discussion above with regard

to the ground on which we institute review of the same claims, we exercise our discretion and decline to institute trial based on those other asserted grounds of unpatentability. *See* 37 C.F.R. § 42.108(a).

## III. CONCLUSION

For the foregoing reasons, based on the present record, we determine that Petitioner has demonstrated that there is a reasonable likelihood that Petitioner would prevail in showing that claims 1–4 of the '720 patent are unpatentable. At this stage of the proceeding, the Board has not made a final determination with respect to the patentability of the challenged claims or any underlying factual or legal issues.

## IV. ORDER

For the reasons given, it is

ORDERED that, pursuant to 35 U.S.C. § 314(a), *inter partes* review is instituted as to the ground of unpatentability that claims 1–4 of the '720 patent would have been obvious over Groenendaal (Ex. 1005) and Leslie (Ex. 1003);

FURTHER ORDERED that *inter partes* review commences on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; and

FURTHER ORDERED that the trial is limited to the ground of unpatentability listed above, and no other ground of unpatentability is authorized for *inter partes* review.

For PETITIONER:

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