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EXHIBIT A

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

JARROW FORMULAS, INC.
Respondent and Requester

v.

SOFT GEL TECHNOLOGIES, INC.
Patent Owner and Appellant

Appeal 2015-007397
Reexamination Control 95/002,396
Patent 8,124,072 B2
Technology Center 3900

Before CHUNG K. PAK, RICHARD M. LEBOVITZ, and JEFFREY B. ROBERTSON, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on the appeal by Patent Owner from the Patent Examiner's final rejection of claims 1–24 in the above-identified *inter partes* reexamination of

EXHIBIT A

United States Patent 8,124,072 B2. The Board's jurisdiction for this appeal is under 35 U.S.C. §§ 6(b), 134, and 315 (pre-AIA). We affirm.

STATEMENT OF THE CASE

The patent in dispute in this appeal is United States Patent 8,124,072 B2 ("the '072 patent") which issued February 28, 2012.

Jarrow Formulas, Inc. ("Requester") requested *inter partes* reexamination of the '072 patent under 35 U.S.C. §§ 311 318 and 37 C.F.R. §§ 1.902–1.997. Request for *Inter Partes* Reexamination dated September 15, 2012 ("Request"). Reexamination was ordered November 23, 2012. The Action Closing Prosecution was mailed July 8, 2013, and a Right of Appeal Notice ("RAN") mailed April 30, 2014 listed pending claims 1–24 as finally rejected.

Patent Owner, Soft Gel Technologies, Inc., who is the real party in interest, appeals the Examiner's final rejection of these claims. Appeal Br. 1. Patent Owner is the Appellant in this appeal. Requester is the Respondent. An oral hearing was heard on December 9, 2015. A written transcript will be entered into the record in due course.

There are related appeals and trials. Patent Owner identifies two District Court actions related to the current reexamination which involves U.S. Patent 7,588,786 ("Khan '786") [1]: Civil Action No. 2:10-cv-08301-PSG-JCx (C.D. Cal.) and Civil Action No. 2:11-cv-00164-PSG-JCx (C.D. Cal.). Appeal Br. 1. The above Civil Actions were consolidated and the District Court granted summary

[1] U.S. Patent No. 7,588,786 B2, issued September 15, 2009, to Mansoor A. Khan and Sami Nazzal. Khan '786 is the basis of anticipation and obviousness rejections in this appeal.

judgment of noninfringement. The decision was appealed to the Federal Circuit which affirmed the judgment under Fed. Cir. R. 36 (entered Oct. 8, 2014) (2014-1020, -1033, -1039).

There are also two related *inter partes* reexaminations, 95/002,411 and 95/002,405, which have been appealed to the Patent Trial and Appeal Board ("PTAB"). A decision affirming the Examiner in Appeal 2015-004072 of Reexamination Control 95/002,411, US Patent 8,147,826 B2, was entered Aug. 31, 2015. A decision in the second appeal, 2015-007926, in Reexamination Control 95/002,405 of US Patent 8,105,583, is entered concurrently with the decision in this appeal. The decisions in this appeal are highly pertinent to the decision in Appeal 2015-004072 as they involve related issues and the same prior art. For this reason, we consider our findings and determinations in this appeal applicable, when relevant, to Appeal 2015-004072.

Claim

Claim 1 is representative of the claims on appeal and reads as follows:

> 1. A soft gelatin capsule, comprising coenzyme Q-10 solubilized in limonene to form a solution, wherein the amount of coenzyme Q-10 in said solution is about 15 percent up to about 60 percent coenzyme Q-10 by weight, with the proviso that the coenzyme Q-10 solubilized in the limonene is not in an emulsion, suspension, or elixir.

Rejections

In the Right of Notice of Appeal, the Examiner rejected claims as follows:

1. Claims 1–3, 6–10, 14–20 and 24 under 35 U.S.C. § 102(a) and (e) as

anticipated by Khan '786, as evidenced[2] by Fenaroli,[3] Duetz (Exhibit B),[4] Mondello (Exhibit C),[5] and IARC (Exhibit D).[6] RAN 8.

2. Claims 4, 11, and 21 under 35 U.S.C. § 103(a) as obvious in view of Khan '786 and Steele[7] as evidenced by Fenaroli, Duetz (Exhibit B), Mondello (Exhibit C), and IARC (Exhibit D). RAN 10.

3. Claim 12 and 22 under 35 U.S.C. § 103(a) as obvious in view of Khan '786 and Motoyama,[8] Patent Owner's admission on Motoyama, as evidenced by Fenaroli, Duetz (Exhibit B), Mondello (Exhibit C), and IARC (Exhibit D). RAN 11.

4. Claim 1–3, 6–10, 14-20 and 24 under 35 U.S.C. § 102(b) as anticipated by Nazzal as evidenced by Fenaroli, Duetz (Exhibit B), Mondello (Exhibit C), and IARC (Exhibit D). RAN 12.

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[2] The Examiner also cited Exhibits E and F, but we have not relied upon them and therefore do not include them in the ground of rejection or in grounds of rejection 2–9.

[3] Giovanni Fenaroli, Fenaroli's Handbook of Flavor Ingredients, vol. 1, p. 389, 2nd edition, CRC Press, Inc. 1975.

[4] Wouter A. Duetz et al., "Biotransformation of D-Limonene to (+) *trans*-Carveol by Toluene-Grown *Rhodococcus opacus* PWD4 Cells," 67(6) Applied Environmental Microbiology 2829–2832 (June 2001)

[5] Luigi Mondello et al., "Multidimensional Capillary GC-GC for the Analysis of Real Complex Samples. 3. Enantiomeric Distribution of Monoterpene Hydrocarbons and Monoterpene Alcohols of Mandarin Oils," 46(1) J Agric. Food Chem. 54-61 (Jan. 19, 1998).

[6] World Health Organization, 56 IARC Monographs on the Evaluation of Carcinogenic Risks to Humans 135-162 (1993).

[7] Steele, EP 0 888 774 A2, published Jan. 7, 1999.

[8] Moyotama et al., Patent Application Laid-Open Disclosure S57-42616, published Mar. 10, 1982.

5. Claims 4, 11, and 21 under 35 U.S.C. § 103(a) as obvious in view of Nazzal and Steele as evidenced by Fenaroli, Duetz (Exhibit B), Mondello (Exhibit C), and IARC (Exhibit D). RAN 15.

6. Claims 12 and 22 under 35 U.S.C. § 103(a) as obvious in view of Nazzal and Motoyama as evidenced by Fenaroli, Duetz (Exhibit B), Mondello (Exhibit C), and IARC (Exhibit D). RAN 16.

7. Claims 1-3, 5–10, 12–20 and 22–24 under 35 U.S.C. § 103(a) as obvious in view of Khan '786, Nazzal, Motoyama, and Patent Owner's admission on Motoyama as evidenced by Fenaroli, Duetz (Exhibit B), Mondello (Exhibit C), and IARC (Exhibit D). RAN 16.

8. Claims 4, 11, and 21 under 35 U.S.C. § 103(a) as obvious in view of Khan '786, Nazzal, Motoyama, Patent Owner's admission on Motoyama, and Steele as evidenced by Fenaroli, Duetz (Exhibit B), Mondello (Exhibit C), and IARC (Exhibit D). RAN 20.

9. Claim 12 and 22 under 35 U.S.C. § 103(a) as obvious in view of Khan '786, Nazzal, Motoyama, Patent Owner's admission on Motoyama, and Davidson[9] as evidenced by Fenaroli, Duetz (Exhibit B), Mondello (Exhibit C), and IARC (Exhibit D). RAN 21.

Background

The '072 patent teaches that CoQ-10 (coenzyme Q10),[10] commonly known as ubiquinone, is essential for the production of cellular energy. '072 patent, col.

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[9] Davidson et al., US 2004/0001874 A1, published Jan. 1, 2004.
[10] For brevity, we use the abbreviation "Q10" throughout this decision. The Examiner also used the abbreviation "Q-10."

1, ll. 16–19. The '072 patent describes clinical studies in which Q10 supplementation has been found to support blood pressure and cholesterol levels and improve cardiovascular health. *Id.* at col. 1, ll. 44–48. The '072 patent discloses that Q10 is sparingly soluble in most hydrophilic solvents, such as water, which limits its bioavailability. *Id.* at col. 1, ll. 51–55. The '072 patent characterized the invention as "the surprising discovery that ubiquinone (CoQ-10) can be readily dissolved in varying concentrations in monoterpenes." *Id.* at col. 2, ll. 46-48. This approach satisfied the "need in the art for an improved methodology to deliver increased amount of bioavailable CoQ-10 to an individual in need thereof." *Id.* at col. 1, ll. 56–58. The monoterpenes described in the '072 patent include limonene and carvone. *Id.* at col. 3, ll. 49–53.

CLAIM INTERPRETATION

Claim 1 is directed to a "soft gelatin capsule" which comprises "co-enzyme Q-10 solubilized in limonene to form a solution." The '072 patent teaches that the "phrase 'sufficient quantity of a monoterpene suitable to solubilize coenzyme Q-10' is therefore intended to mean that that amount of a monoterpene that will dissolve CoQ-10 under a given set of conditions, generally, those at ambient temperature." '072 patent, col. 3, ll. 11-16. In this case, the monoterpene is limonene. We therefore interpret the term "solubilize" as it is used in the claim means "dissolve."

REJECTIONS

4. ANTICIPATION REJECTION BY NAZZAL

Claim 1 is directed to a "soft gelatin capsule" comprising "coenzyme Q-10 solubilized in limonene to form a solution." The Q10 is present in an amount of about 15 percent up to about 60 percent coenzyme. The claim contains a "proviso" that "the coenzyme Q-10 solubilized in the limonene is not in an emulsion, suspension, or elixir."

Rejection

The Examiner found that Nazzal describes "a drug delivery system containing coenzyme Q-10 solubilized in lemon oil that can be filled into a soft gelatin capsule." RAN 12. Citing Fenaroli, the Examiner found that lemon oil contains 90% or more limonene, and of the limonene, "d-limonene constitutes 92-96% of lemon peel oil (Exhibit B, page 2829), and amounts to 98.1 % (Exhibit C, page 59, Table 6) or 98-100% of the lemonone [sic, limonene] in lemon oil (Exhibit D, page 135)." *Id.* at 12–13. Using these values, the Examiner calculated that Nazzal describes a Q10-lemon oil binary system comprising "about 36%, 45% and 54% by weight d-limonene, which is of sufficient quantity to melt and solubilize coenzyme Q10 to form a solution at about 33°C, 26°C and 24°C respectively." *Id.* at 13. The Examiner also found that Q10 is present in amounts of 60%, 50%, and 40% by weight in the oily phase of lemon oil, meeting the weight limitation of claim 1. *Id.*

Claim 1 also requires the Q10 is solubilized in d-limonene and "not in an emulsion, suspension, or elixir" in the capsule. The Examiner found that Q10 is solubilized in lemon oil, and when present in the capsule, no water is present so the

SNEDDS [self-nanoemulsified drug delivery system] is not an emulsion until introduced into an aqueous medium. *Id.* at 9.

Discussion

Emulsion

Patent Owner contends that Nazzal does not anticipate the claims because Nazzal teaches that the lemon oil and Q10 are combined with a surfactant, co-surfactant, and other ingredients form an emulsion which is excluded by the claim. Appeal Br. 28–29. As evidence of this, Patent Owner identified the following disclosure from Nazzal:

> The eutectic-based self-nanoemulsified drug delivery system (SNEDDS) of CoQ_{10} was prepared as follow[s]: CoQ_{10} and lemon oil at a ratio of 1:1 were accurately weighed into screw-capped glass vial and melted in water bath at 37°C. Cremophor EL and Capmul MCM-C8 were added to the oily mix at a final concentration of 26.9%w/w each. The resultant emulsion was mixed with a stirring bar until a transparent solution of SNEDDS was obtained. The SNEDDS were then allowed to cool at ambient temperature for 24 hrs until a viscous paste was obtained. Nanoemulsion adsorbed granular material was obtained from a mixture of SNEDDS paste, copolyvidone (Kollidon VA 64), maltodextrin (Glucidex IT 12), and microcrystalline cellulose (Avicel) . . .

Nazzal 80.

> A eutectic mixture of CoQ_{10} with lemon oil could be used to produce stable nanoemulsion in aqueous medium when mixed with a proper blend of surfactants and cosurfactants.

Id. at 243.

A preponderance of the evidence does not support Patent Owner's contention that composition comprising Q10, lemon oil, surfactant Cremophor EL,

and cosurfactant Capmul MCM-C8 are in the form of an emulsion. The evidence is outlined below:

1. Nazzal expressly teaches that a self-emulsifying drug delivery system is not a microemulsion:

> Self-emulsifying drug delivery systems (SEDDS) and self-microemulsifying drug delivery systems (SMEDDS) are not microemulsions, although they may be considered to be a closely related system. The key difference between the two preparations is the optical clarity and the finer droplet size achieved when SMEDDS are dispersed into the aqueous phase . . . A SMEDDS typically comprises a mixture of surfactant, oil and drug (known as the concentrate) which when introduced into the body is rapidly dispersed to form droplets of approximately the same size range as those observed in microemulsion systems . . . Once dispersed, such systems would be expected to self-emulsify rapidly in the aqueous contents of the stomach and to behave *in vivo* much the same way as oil-in-water (o/w) microemulsions. . . . . SEDDS and SNEDDS can therefore be defined as "isotropic solutions of oil, surfactant, co-surfactant, and drug which form o/w (micro) emulsions when introduced into aqueous phases under gentle agitation."

Id. at 19–20 (internal citations omitted) (emphasis added).

As the passage reproduced above shows, Nazzal teaches that the self-microemulsifying drug delivery systems "are not microemulsions." *Id.* Rather, when "dispersed" in an aqueous phase, the SNEDDS self-emulsifies to form an oil-in-water emulsion. *Id.* This description is consistent with the description on pages 71–72 of Nazzal, and elsewhere, where he describes stirring formulations of Q10, oil, surfactant, and co-surfactant in water, and observing that a spontaneous transparent emulsion is formed. *Id.* at 27-34; 121–132.

2. Nazzal distinguishes between microemulsions and self-emulsifying vehicles, indicating that the SNEDDS is not in the form of a microemulsion:

> The delivery of cyclosporine A via microemulsion formulations and the superiority of the Neoral® microemulsion preconcentrate . . . has been demonstrated on several occasions . . .
>
> To date, microemulsion and self-emulsifying vehicles have been shown to be able to protect labile drug, control drug release, increase drug solubility, increase bioavailability and reduce PK and PD response variability.

Id. at 26.

3. Despite the mention of forming an emulsion on page 80, other parts of Nazzal refer to melting Q10, the essential oil, and surfactant, and specifically at body temperature before being dispersed into an emulsion in the body's aqueous environment. *Id.* at 121, 132. For example, in Nazzal's description of making an HPMC capsule, he describes adding the surfactant and cosurfactant to an oily mix of the Q10 and lemon, and "[w]hile molten," filling the HPMC capsules. *Id.* at 71. Nazzal further describes introducing the "pre-melted" formulation into water, gently stirring, and then observing the "tendency to spontaneously form a transparent emulsion." *Id.* at 72. Thus, these sections refer to an emulsion when the formulation is introduced into water, but not before. Similarly, the section on page 243 of Nazzal cited by Patent Owner states the formulation produces a "stable nanoemulsion in aqueous medium" (emphasis added), but makes no mention of the formulation, itself, being in the form of an emulsion prior to contact with the water.

4. The Examiner's definition of "emulsion" does not support the finding that mixture of Q10, volatile oil, surfactant, and cosurfactant is an emulsion. The Examiner adopted the following definition of emulsion:

> A substantially permanent mixture of two or more liquids which do not normally dissolve in each other but which are held in suspension, one in the other. The suspension is usually stabilized by small amounts of additional substances known as emulsifiers.

RAN 4.

As discussed in detail below, a preponderance of the evidence indicates that Q10 dissolves in lemon oil dissolve. Consequently, there does not appear to be "two or more liquids" present "which do not normally dissolve in each other." On the other hand, when SNEDDS is introduced into an aqueous environment, the lemon oil/Q10 and water serve as two liquids which do not dissolve in each other, but rather form an emulsion by self-emulsification as described in Nazzal.

Consistent with this definition are the statements made during the prosecution of the '072 patent when the proviso was added excluding an "emulsion":

> In contrast to the presently claimed method, the Examiner points out that "Garti et al. disclose compositions, nano-scale emulsions." Office Action, p. 3 and 5. Garti does not contradict the Examiner's characterization, rather Garti more precisely describes the emulsion as "nano-sized structured concentrates.., of at least two immiscible liquids (water and oil) with the aid of a surfactant, co-surfactant and co-solvent." . . . Thus, Garti's invention is a multi-component formulation of the type expressly proviso'd out in present claims 14 [present claim 1] and 22.

Remarks 7 (Oct. 19, 2009) (emphasis added)

In other words, the term "emulsion" requires two immiscible liquids, but there is inadequate evidence that two immiscible liquids are present in the formulation comprising Q10, lemon oil, surfactant, and co-surfactant because as explained in more detail below, the evidence supports the finding that Q10 dissolves in lemon oil. Consequently, Nazzal's use of the term "emulsion" on page 80, when the surfactant and co-surfactant are added to the oily mix of Q10 and lemon oil appears to be in a different context than the definition adopted by the

Examiner and proposed by Patent Owner when the term was added to claim 1 by amendment.

"coenzyme Q-10 solubilized in limonene to form a solution"

The claims all require the coenzyme Q10 to be "solubilized in limonene to form a solution."

The Examiner found that Nazzal describes "a drug delivery system containing coenzyme Q-10 solubilized in lemon oil that can be filled into a soft gelatin capsule," where the lemon oil "contains 90% or more limonene (Fenaroli, page 389), which is mostly or all d-limonene," constituting "92-96% of lemon peel oil (Exhibit B, page 2829), and amounts to 98.1 % (Exhibit C, page 59, Table 6) or 98-100% of the limonene in lemon oil (Exhibit D, page 135)." RAN 12–13. The Examiner found that Nazzal "shows that as the relative amount of lemon oil is increased, the temperature at which the coenzyme Q10 melts and solubilizes in solution can be reduced from about 51°C (melting temperature of coenzyme Q10) to below room temperature (pages 112–115)." *Id.* at 13.

The Examiner acknowledged that Nazzal describes melting the Q10 in lemon oil, but stated that the recited language in the claims does "not exclude solubilizing or dissolving via melting." *Id.* at 22. The Examiner further stated that Patent Owner has not demonstrated "any difference between the prior art binary mixtures of coenzyme Q10 and lemon oil (d-limonene) and the claimed composition comprising coenzyme Q10 and d-limonene."[11] *Id.*

[11] The Examiner referred to d-limonene, but the claims are not limited to this form, but rather recite "limonene" which would include both the d- and l-forms.

The following findings of fact ("FF") are pertinent to the Examiner's determination that Nazzal anticipates the claimed subject matter:

FF1. Nazzal teaches that Q10 and a volatile essential oil (L-menthol, spearmint oil, lemon oil and anise oil) were mixed and then heated to different temperatures to determine the temperature at which the mixture melted. Nazzal 112–115; Figures 4.8–4.12.

FF2. Specifically, Fig. 4.13 of Nazzal shows a temperature range, of about 15°C to about 50°C, over which Q10 was melted with the essential oil using different weight/weight ratios of Q10 to essential oil.

FF3. Figs. 4.8–4.12 of Nazzal show the differential scanning calorimetry (DSC) thermograms of various volatile essential oils and Q10. The data in these figures was used to construct the graph in Fig. 4.13. *Id.* at 112-115. Fig. 4.11 shows the DSC thermogram for Q10 and lemon. Each point in Fig. 4.13 was determined from a DSC thermogram of Q10 and a specific amount of the essential oil.

FF4. The data in Figs. 4.8 to 4.13 show that the binary combination of Q10 and essential oil (such as lemon oil) formed a melted composition at a specific temperature for a specific ratio of Q10 to oil.

Issue

The issue is whether Nazzal's teaching of a melted composition of Q10 and lemon oil anticipates the claimed "coenzyme Q-10 solubilized in limonene to form a solution." In other words, does melting Q10 in lemon oil (FF1) result in a composition in which Q10 is solubilized, namely dissolved, in the limonene?

Since Nazzal does not expressly teach that the Q10 dissolves in limonene, the rejection is based on "inherency," that is, while Nazzal does not describe its composition with the same terms recited in the claim, the claimed composition would be a necessary result of making the composition described in Nazzal.

> [A] prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent to it. . . . Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.

MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999).

Anticipation does not require the skilled worker to have recognized that the Q10 was dissolved in the d-limonene as long as it would happen each time the directions in Nazzal were followed.

Discussion

Patent Owner contends that Nazzal does not anticipate the claimed "solubilized coenzyme Q-10 composition" comprising limonene because Nazzal "does not disclose that [coenzyme] Q-10 can be dissolved in lemon oil, and instead teaches melting point reduction as an alternative way to liquefy coQ-10 precisely because it is difficult to dissolve." Appeal Br. 24. Patent Owner argues that Nazzal does not provide "a solution in which coenzyme Q-10 is dissolved," but rather "states that the 'poor water solubility' of coQ-10 is overcome by reducing the melting point of coQ10, so that it becomes a liquid at or below 30°C." *Id.* at 25. To support this position, Patent Owner cites the following disclosure from Nazzal:

> FF5
>
> Due to the limited solubility of CoQ-10 in fixed oils and triglycerides, the melting point depression method using essential oils provides an attractive alternative for the preparation of an emulsified formulation.

Nazzal 115.

Patent Owner further argues that Nazzal "distinguishes between melting and dissolving and states that melting is an attractive alternative to traditional approaches that unsuccessfully sought to dissolve coenzyme Q-10." Appeal Br. 25. To support this position, Patent Owner points to the following disclosure in Nazzal:

> FF6
>
> In a eutectic-based self-nanoemulsifying, the melting point depression method allows the oil phase containing the drug itself to melt at body temperature from its semisolid consistency and disperse to form emulsion droplets in nanometer size range.

Id. at 112.

Patent Owner also cites a District Court Order ("Dist. Ct. Order") in an infringement action in the United States District Court Central District of California (CV 10-8301 PSG) asserting Khan '786 against, *inter alia*, Patent Owner. *See* 2012 WL 3186576 (2012). In the District Court Order, the court rejected the position that melting as used in Khan '786 is "synonymous" with dissolving. Dist. Ct. Order 11. The District Court decision was affirmed by the Federal Circuit under Fed. Cir. R.36 (Oct. 8, 2014, 2014-1020, -1033, -1039).

Nazzal is the Ph.D. dissertation of one of the co-inventors of Khan '786. According to Patent Owner, Nazzal's dissertation "resulted in the Khan patent application." Appeal Br. 23. Patent Owner states the "relevant disclosure of

Nazzal is the same as the disclosure in the Khan patent, and thus suffers from the same disclosure deficiencies as Khan." *Id.* Patent Owner did not distinguish between the disclosure in Khan '786 and Nazzal, but rather appears to have made the same arguments for both publications. *Id.* at 24-29. Consequently, we find that the District Court's findings regarding Khan '786 are applicable to Nazzal.

The Order construed "melting" to be "'a phase transition from solid to liquid' through the application of heat." Dist. Ct. Order 10. The district court, however, did not provide a definition of "dissolve."

FF7. Because no definition is of record for us to consider, we have consulted a general chemistry textbook to determine the meaning of "dissolve" and "dissolving." "Dissolve" is defined in the following manner: "When a solute dissolves, the individual particles of solute become surrounded by solvent particles" to produce a "solution."[12] A "solution" is a homogeneous combination of solute and solvent particles. *General Chemistry – Principles, Patterns, and Applications*[13] 1172 (hereinafter, "*General Chemistry*.") See also RAN 4 ("A true solution is a homogeneous mixture of two or more substances.")

The Examiner found that melting is "closely related" to dissolving because both involve energy changes. RAN 23. The Examiner did not cite support for this

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[12] *The Basics of General, Organic, and Biological Chemistry* (2011), v. 1.0, Ball, David, W., Hill, John W., and Scott, Rhonda, J., Section 9.3, "The Dissolution Process," Flat World Education, Inc. (2015). Accessed at http://catalog.flatworldknowledge.com/bookhub/reader/2547?e=gob-ch09_s03 (Dec. 11, 2015). Hereinafter, "*Chemistry Basics*."

[13] Averill B. and Eldredge, P. (2011) http://www.saylor.org/site/textbooks/General%20Chemistry%20Principles,%20Patterns,%20and%20Applications.pdf

statement apparently because the statement reflects well known principles in chemistry. The Examiner's finding is factually supported as follows:

> FF8
>
> Physical changes, such as melting or vaporization, and chemical reactions, in which one substance is converted to another, are accompanied by changes in enthalpy [energy change]. Two other kinds of changes that are accompanied by changes in enthalpy are the dissolution of solids and the dilution of concentrated solutions.

General Chemistry 444.

FF9. When a solute dissolves in a solvent, "energy is required to overcome the intermolecular interactions in a solute." *Id.* at 1173. Similarly, the "melting point" is when the ions or atoms in a solid have enough energy to overcome the intermolecular attractive forces which hold them together. *Id.* at 684, 795, 981, 985, 1029, 1071.

Thus, as found by the Examiner, "melting" is closely related to "dissolving" because of the change in energy when the intermolecular interactions between the atoms in the solid are overcome as the solid melts or as the solute particles in the solid dissolve in the solvent. A key difference between melting and dissolving is that melting involves only a change in state of the solid into a liquid when the intermolecular forces that hold the atoms in the solid together are overcome, while dissolving involves overcoming the attractive forces between the atoms in the solid and mingling the solid atoms homogenously with solvent particles. When a solid dissolves in the solvent, it could just as well be said that it "melts" because, as with the melting process, the intermolecular forces that hold the solid atoms together are overcome allowing it to become dispersed in solvent.

The next question is whether the Q10 forms a solution when it melts in the presence of the lemon oil. The Examiner's position is that it does because of the close relationship between melting and dissolving, i.e., melting results in overcoming the intermolecular interactions of the atoms in the solid, permitting them to disperse within the lemon oil solvent as would happen when the intermolecular forces are overcome in dissolving. The Examiner's reasoning is supported by Dr. Nazzal's testimony in his declaration in which he describes his work reported in the Khan '786 patent. RAN 26–28. Dr. Nazzal testified (emphasis added):

> 4. The '786 Patent [Khan] describes and teaches the surprising and unexpected discovery that a sufficient amount of volatile essential oil reduces the melting point of CoQ10 to 37°C or below to thereby liquefy and solubilize the CoQ10 at or below body temperature.
>
> 5. At the time of our invention, I was not aware of any CoQ10 formulation in commercial use or in the literature that contained CoQ10 that was solubilized with a volatile essential oil or solubilized with a sufficient amount of a volatile essential oil that would reduce CoQ10's melting temperature.

Dr. Nazzal thus explains when the Q10 is melted to a liquid it is "solubilized," namely dissolved in the essential oil (*see* "Claim Interpretation" above finding that solubilize means dissolve).

In sum, a preponderance of the evidence supports the conclusion that when the Q10 and lemon oil form a mixture upon heating (FF1–FF4), the Q10 melts and dissolves in the lemon oil.

Patent Owner's argument that Khan '786's use of the term "solubilize" is not the same as "dissolve" is unavailing. Appeal Br. 10–13. Patent Owner contends that Khan '786 and Nazzal distinguish between "dissolve" and

"solubilize." Rebuttal Br. 2. Specifically, Patent Owner argues that "solubilize" is used in Khan '786 in the context of utilizing surfactants. *Id.* at 3.

In our opinion, it is not clear cut that Khan '786 and Nazzal use the terms "dissolve" and "solubilize" in all instances to mean different chemical processes. For example, in the passage reproduced below, Nazzal refers to dissolving Q10 in acetone and then to "solubilized" Q10 in acetone, suggesting that in this instance the terms are used in the same way.

> To eliminate the effect of temperature on the integrity CoQ10, stock solution (0.1 mg ml^{-1}, 0.1% Cremophor EL) was prepared by dissolving 100 mg of CoQ_{10} in 3 ml of acetone. One gram of Cremophor EL was added and mixed with the solution and subsequently diluted to 1 liter with distilled water. Similarly, to evaluate the effect of Cremophor EL concentration on CoQ_{10} analysis, a stock solution (0.1 mg ml^{-1}, 1% Cremophor EL) was prepared by mixing solubilized CoQ_{10} in acetone with 10 grams of Cremophor EL. Assay validation was performed as described above.

Nazzal 67 (emphasis added).

Although Patent Owner attempts to establish that "solubilize" requires the presence of solubilizing agents (Appeal Br. 13), Dr. Nazzal does not refer to the presence of a solubilizing agent in his statements in paragraphs 4 and 5 of his declaration. Moreover, Patent Owner has not explained why "solubilizing" a drug with a "solubilizing agent" would not result in the drug being dissolved in the solubilizing agent. Patent Owner has largely focused on word definitions, and perhaps the imprecise and loose use of the words, without explaining the actual chemical processes that occur when a compound is dissolved or solubilized.

Nonetheless, the rejection is based on inherency, and even if Khan '786 and Nazzal use the terms "dissolve" and "solubilize" to mean different chemical processes, the issue is not whether the two publications described Q10 dissolved in

lemon oil, and its main constituent limonene, but whether, when Khan '786 and Nazzal are followed, would the necessary result be Q10 dissolved in limonene.

Patent Owner also contends that the "mechanism" by which "one gets to a liquid solution . . . cannot be ignored." Appeal Br. 13. The Examiner has not ignored this step. As explained, when heat is applied to the binary combination of lemon oil and Q10, the attractive forces in the atoms are overcome in the Q10 and it dissolves in the lemon oil. Patent Owner denies that dissolving occurs, but has offered no alternative explanation as to what happens to the atoms of Q10 and lemon oil upon the application of heat.

The District Court Order is not inconsistent with the conclusion that the Q10 dissolves in the lemon oil. The District Court distinguished melting from dissolving, a finding that does not exclude there from being similarities between the two processes as discussed above. Moreover, the District Court in the Order acknowledged that the melting point reduction process in Khan '786 in which a eutectic was formed resulted in the Q10 dissolved in lemon oil: "The fact that the melting point reduction is used as a means to solubilize or dissolve and as a basis for distinguishing traditional methods indicates that melting is distinct from dissolving or solubilizing." Dist. Ct. Order 13 (emphasis added). In other words, while the District Court recognized that the "melting point reduction" method is different from dissolving because a reduction in melting temperature is observed in the former and results in "a change in the physical properties" of Q10, it specifically stated the melting point reduction method was a "means to solubilize or dissolve" the Q10. *Id.* The mechanisms may be different, but it is the result which is claimed, not the mechanism, which is relevant to the claims at issue, as there is no temperature limitation set forth in the claims.

limonene

FF10. The Examiner found that lemon oil contains 90% or more limonene (citing Fenaroli on page 389), which "is mostly or all d-limonene (Exhibits B-F)."[14] RAN 12.

FF11. The Examiner further found that "Lemon oil contains 90% or more limonene (Fenaroli, page 389), which is mostly or all d-limonene (Exhibits B-F). Indeed, d-limonene constitutes 92-96% of lemon peel oil (Exhibit B, page 2829), and amounts to 98.1 % (Exhibit C, page 59, Table 6) or 98-100% of the limonene in lemon oil (Exhibit D, page 135." *Id.* at 12–13. The Examiner's findings regarding these publications are factually supported.

Based on these values, the Examiner found that the binary composition of Q10 and lemon oil as shown in Nazzal's Fig. 4.13, contains "about 36%, 45% and 54% by weight d-limonene (in 40%, 50% and 60% by weight lemon oil) in a mixture with 60%, 50% and 40% by weight of coenzyme Q10 respectively." *Id.* at 29. The Examiner concluded that in the binary composition "coenzyme Q10 melts and solubilizes at about 33°C, 26°C and 24°C respectively, indicating that d-limonene (lemon oil) is suitable for dissolving coenzyme Q10 at ambient temperature or below." *Id.*

Patent Owner disputes the Examiner's finding that lemon oil is always necessarily[15] d-limonene or 90% d-limonene, citing the Lota and Steuer publications as evidence. Appeal Br. 15-16. Patent Owner states:

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[14] We have not considered Exhibits E and F.

[15] "[A] prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent,

> Patent Owner has submitted evidence that the amount of limonene in lemon oil is less than 40%. See Lota at 797, Table 1 (Ex. V). Accordingly, Exhibits B, C and D, in view of Lota and Steuer, do not meet the Office's burden to show anticipation by inherency; they do not "make clear" that lemon oil is always "necessarily" d-limonene or 90% d-limonene

Id. at 16.

While we have concluded that Q10 dissolves in lemon oil when melted, the claim requires that Q10 be dissolved in the limonene present in the lemon oil. The Examiner's reasoning for finding that it is the limonene that dissolves the Q10 appears to be based on the fact that limonene is the main constituent of lemon oil containing as much as 90%. Specifically, Exhibits B, C, and D support the Examiner's position. FF10, FF11. Patent Owner's countervailing evidence is that the amount of *limonene* in lemon oil can be less than 90%, depending on the source.

Even if it true that the content of limonene is than the 90% value relied upon by the Examiner, this does not answer the *issue* in this rejection, i.e., whether the limonene in Nazzal's lemon oil dissolves the Q10 when the lemon oil and Q10 are melted together. Thus, even if the amount of limonene present in the lemon oil/Q10 mixture described in Nazzal is less than the lower limit of 36% by weight calculated by the Examiner (RAN 13), there still must be evidence that such lower amounts would or would not dissolve Q10.

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in the single anticipating reference." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005) (citing *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991)).

The Examiner had basis to find that the Q10 dissolves in the limonene because, as discussed above, the Q10 dissolves in the lemon oil and a significant amount of limonene is present in the lemon oil. Patent Owner argues about the content of limonene in lemon oil, but fails to provide evidence that, if the particular species or strain which is said to contain less limonene than the 90% value assumed by the Examiner had been used in Nazzal,[16] the amounts of d-limonene would have been insufficient to dissolve the recited amounts of Q10.

In our opinion, this controversy about the amounts of limonene and limonene in lemon oil that has occupied the Examiner, Patent Owner, and Requester begs the question of how much limonene is necessary to dissolve the recited amounts of Q10. On this pivotal question, the evidence is that 1) lemon oil solubilizes and dissolves Q10, and 2) limonene is principal component of it, giving the Examiner reasonable factual basis to conclude that even lemon oils with less than 90% limonene would have sufficient d-limonene present to dissolve Q10.

The lower value of 38.1% identified in one species in Lota (Table 1, "Bor") is still about a third of the higher values; indeed, there is no evidence that this species of lemon oil peel was available to Nazzal.

Under *In re Best*, 562 F.2d 1252 (CCPA 1977), Patent Owner has the burden to prove that the recited amounts of Q10 would not be dissolved in the lemon oil of Nazzal.

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the

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[16] Lemon peel oils: "Limonene was always the main constituent (38.1-95.8%) of all oils." Lota, page 799.

> prior art products do not necessarily or inherently possess the characteristics of his claimed product.
>
> . . .
>
> Whether the rejection is based on "inherency" under 35 U.S.C. § 102, on "prima facie obviousness" under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products.

Best, 562 F.2d at 1255 (CCPA 1977) (footnote omitted). Patent Owner did not meet this burden.

In sum, the fact that Nazzal's lemon oil was not necessarily 90% limonene (Appeal Br. 13–14) does not undermine the Examiner's finding that Nazzal anticipates the claimed subject matter. In view of this evidence, we conclude that a preponderance of the evidence supports the Examiner's finding that Nazzal necessarily and inherently disclosed Q10 dissolved in limonene.

Khan (2004)

Patent Owner argues that a subsequent publication by Khan – Khan (2004)[17] – demonstrates that the lemon in Nazzal "was not d-limonene or 90% d-limonene." Appeal Br. 15. According to Patent Owner, Khan (2004) is "a separate study analyzing d-limonene and its ability to reduce the melting point of coenzyme Q10." *Id* at 15. Patent Owner contends:

> If the lemon oil used in Khan and Nazzal were d-limonene or 90% d-limonene, then there would be no reason for Dr. Khan subsequently to

[17] Anitha Palamakula, Mahmoud Soliman, Indra K. Reddy, and Mansoor A. Khan, "Preparation and *In Vitro* characterization of Self-Nanoemulsified Drug Delivery Systems of Coenzyme Q10 Using Chiral Essential Oil Components," Pharmaceutical Technology 74–88 (October 2004).

> study and publish findings on whether d-limonene could be used to reduce the melting point of coenzyme Q10.

Id.

Patent Owner has not provided adequate evidence that subsequent work by Khan's group using d-limonene rather than lemon oil reasonably means that Khan did not believe the lemon oil in the Nazzal was not predominantly limonene. Khan (2004) states that the reason for its study was "to study natural substance such as chiral components of essential oils for solubilizing drug compounds." Khan (2004) 74. Khan (2004) further states that limonenes exist in two chiral conformations and the R-(+) form, also known as d-limonene. *Id.* Furthermore, Khan states that that "[r]esearch in the food industry has demonstrated R-(+)-limonene in microemulsions as vehicles to enhance the solubilization of natural food supplements," but acknowledges that the "available literature is scare . .. about using these components to prepare SNEDDS." *Id.* Thus, it appears Khan (2004)'s reason for studying d-limonene was its interest in chiral component.

Dependent claims

Patent Owner did not provide separate reasons for the patentability of claims 2, 6–10, and 15. Appeal Br. 21. Thus, these claims fall with independent claim 1. 37 C.F.R. § 41.67(c)(vii).

5. OBVIOUSNESS REJECTION OVER NAZZAL AND STEELE

The Examiner found that Nazzal does not disclose rice bran oil as a carrier as specified in claims 4, 11 and 21. RAN 15. However, the Examiner found that rice bran oil as a carrier in a coenzyme Q10 soft gelatin formulation was known in

the art at the time of the invention as specifically described by Steele (abstract; page 3, lines 4-5). *Id.* Accordingly, the Examiner concluded it would have been obvious to include the rice bran oil as a carrier in Nazzal's solubilized coenzyme Q10 formulation to arrive at the claimed invention with a reasonable expectation of success. *Id.*

Patent Owner argues that Steele does not "remedy the deficiencies of Nazzal." Appeal Br. 29. Because we determined that these arguments are unpersuasive, the rejection of claims 4, 11, and 21 are affirmed for the reasons set forth by the Examiner.

6. OBVIOUSNESS REJECTION OVER NAZZAL AND MOTOYAMA

The Examiner found that Nazzal does not disclose fish oil as a carrier as recited in claims 12 and 22. RAN 16. However, the Examiner found that including fish oil in a coenzyme Q 10 formulation was known in the art at the time of the invention as described by Motoyama (page 1, right col.; page 5, right col.). *Id.* Accordingly, the Examiner concluded it would have been obvious to include fish oil in Nazzal's solubilized coenzyme Q10 formulation to arrive at the claimed invention with a reasonable expectation of success. *Id.*

Patent Owner argues that Motoyama does not "remedy the deficiencies of Nazzal." RAN 30. Because we determined that these arguments are unpersuasive, the rejection of claims 12 and 22 are affirmed for the reasons set forth by the Examiner.

7-9. OBVIOUSNESS REJECTIONS BASED ON MOTOYAMA

The Examiner found that Motoyama describes a soft gelatin capsule comprising Q10 dissolved in carvone, which includes l-carvone derived from spearmint oil and peppermint oil and d-carvone from caraway seed oil. RAN 16-17. The Examiner stated that it would have been obvious to have utilized limonene[18] instead of a carvone-containing oil because both were known to be effective in solubilizing Q10 as demonstrated by Khan '786. *Id.* at 18.

In this case, we find there is adequate evidence that one of ordinary skill in the art would have had reason to try limonene to dissolve Q10 with a reasonable expectation of success.[19] The following facts are pertinent to this determination:

FF12. Motoyama teaches that carvone, a monoterpene ('072 patent, col. 4, ll. 52-56), dissolves Q10. Motoyama 5 (col. 2) ("[C]arvone is a particularly preferred oil due to good solubility for ubiquinone and the property of dissolving an equal weight of ubiquinone at room temperature.").

FF13. Motoyama teaches that "refined oils that contain carvone (such as peppermint oil, spearmint oil, or the like) are preferred for the present invention due to the ability to dissolve ubiquinone well." *Id.*

FF14. Khan '786 discloses that essential oils, such as menthol, peppermint oil, spearmint oil, and lemon oil lower the melting temperature of Q10, making

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[18] Both the Examiner and Patent Owner in their arguments refer to "d-limonene." However, the claims do not require d-limonene.

[19] To decide whether a composition would have been obvious in light of the prior art, it must be determined whether, at the time of invention, "a person of ordinary skill in the art would have had reason to attempt to make the . . . [composition], . . . and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007).

them useful in a delivery system for Q10. Khan '786, col. 6, ll. 24–27, col. 6, l. 65 to col. 7, l. 35.

FF15. D-limonene is a monoterpene ('072 patent, col. 4, ll. 52-56) and the main constituent of lemon peel oil (Duetz 2829 (Exhibit B)("D-Limonene is the main constituent of orange and lemon peel oil (92 to 96%) . . ."); (IARC 135 (Exhibit D) ("the d form [of limonene] comprises 98-100% of the limonene in most citrus oils (family Rustaceae)")); Mondello, Table 6 (Exhibit C)("limonene (4R)(+) 98.1"))

FF16. Nazzal recommended for future studies that "[c]hemical components of essential oils such as limonene, menthone, and carvone can be evaluated for their potency in exerting a eutectic effect." Nazzal 246.

Discussion

A preponderance of the evidence supports the Examiner's determination that one of ordinary skill in the art would have had reason to utilize limonene to dissolve Q10.

First, Motoyama teaches that another monoterpene dissolves Q10 and teaches that some of the same oils (spearmint, peppermint) described as effective by Khan '786 are preferred for their ability to dissolve Q10.[20] FF12–FF14.

[20] The '072 patent described its invention as "the surprising discovery that ubiquinone (CoQ-10) can be readily dissolved in varying concentrations in monoterpenes." '072 patent, col. 1, ll. 62-64 or 2:46-48. However, it appears that Motoyama had at least already discovered the Q10 could dissolve in the monoterpene carvone, providing the same solution to the problem identified in the '072 patent of delivering increased amounts of bioavailable Q10. *Id.* at col. 1, ll. 55–58.

Because of the overlap in disclosure of essential oils between Motoyama and Khan '786, one of ordinary skill in the art would have had reason to have used Khan '786's oils in Motoyama's method in amounts sufficient to dissolve Q10, with a reasonable expectation that they would work. That is, since Motoyama teaches that spearmint and peppermint oil dissolve Q10, and Khan '786 teaches using these same oils in conjunction with Q10, the skilled worker would have had basis to believe that Khan '786's lemon oil, when used in a sufficient amount, would work in Motoyama's method to *dissolve* Q10.

Second, while Khan '786 does not identify limonene as a component of lemon oil, limonene is a main constituent of lemon peel oil. FF11, FF12.

The skilled worker would have had reason to use limonene in Motoyama's method because it is a monoterpene like Motoyama's carvone (FF13, FF15), and Nazzal explicitly suggested d-limonene for future studies (FF16). Nazzal also suggested evaluating carvone for its potency in exerting a eutectic effect when combined with Q10 (FF16), further indicating the interchangeability of carvone and d-limonene, or at least the reasonable belief that they would have similar properties.

Patent Owner argues that Khan '786 does not teach that lemon oil or d-limonene can be used to dissolve Q10. Appeal Br. 31–32. Patent Owner argues that, "[o]n the contrary, [] Khan teach[es] melting point reduction as an alternative . . . approach to liquefying CoQ-10, precisely because it is difficult to dissolve." *Id.* at 30-31. Furthermore, Patent Owner contends there would be no reasonable expectation of success since Khan '786 is "directed to reducing the melting point of coenzyme Q-10, not dissolving it." *Id.* Patent Owner states that Khan '786 "teaches away" from utilizing d-limonene to dissolve Q10 because Khan '786 uses

"melting point reduction because coenzyme Q-10 is difficult to dissolve." *Id.* at 32.

Patent Owner argues that Khan '786's subsequent publication, Khan (2004), investigating d-limonene is evidence of nonobviousness:

> If it was obvious at the time of the '072 patent application, that d-limonene could be used to reduce the melting point of CoQ-10, then Khan himself [in Khan 2004], would not have been investigating subsequently whether d-limonene could be so-used. Similarly, if it was obvious that d-limonene could be substituted for Motoyama's carvone, then Khan would not have been teaching melting point reduction as an alternative to address the fact that CoQ-10 is difficult to dissolve.

Id. at 33.

Patent Owner's arguments are not supported by adequate evidence of record. Even if the disclosed mechanisms are different – where Khan '786 describes "melting" Q10 and Motoyama describes "dissolving" Q10 – Motoyama specifically teaches that spearmint and peppermint oils dissolve Q10 (FF13) and these same oils are described by Khan '786 as depressing the melting temperature of Q10 (FF14). Consequently, in view of Motoyama, the skilled worker would have recognized that certain oils that depress the melting temperature of Q10 also dissolve it when an adequate amount of such oil is used for a given amount of Q10. Based on this, the skilled worker would have had reason to use lemon oil and its main constituent d-limonene in Motoyama's method with a reasonable expectation that it would work because other oils shown to depress the melting temperature of Q10 were shown in Motoyama's experiments to dissolve it.

We do not agree that that Khan '786's later experiments with d-limonene is evidence of nonobviousness. Nazzal expressly suggested evaluating d-limonene

(FF16), providing explicit evidence that one of ordinary skill in the art had reason to use it at the time of the invention. In view of this explicit suggestion in Nazzal, one of ordinary skill in the art would had reason to use d-limonene in Motoyama's method, as well, since d-limonene is a monoterpene like carvone which had been shown to dissolve Q10. Indeed, it was later shown by Khan (2004) that d-limonene dissolves Q10. Khan (2004) states "CoQ is fairly soluble in monoterpenes, R-limonene [d-limonene] (571.6 ± 5.03 mg/mL)." Khan (2004) 78.

As held in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421(2007):

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

There is no persuasive evidence of record that one of ordinary skill in the art would have had "to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful." *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988); *Bayer Schering Pharma AG v. Barr Labs., Inc.*, 575 F.3d 1341, 1347 (Fed. Cir. 2009).

For the foregoing reasons, we conclude that a preponderance of the evidence supports the Examiner's determination that claim 1 is obvious in view of Motoyama, Khan '786, Fenaroli, Exhibits B, C, and D, and Nazzal. Claims 2, 3, 5–10, 12–20, and 22–24 were not argued separately and thus fall with claim 1.

Claims 4, 11, 12, 21, and 22

Claims 4, 11, 12, 21, and 22 are further rejected based on the Steele and Davidson. RAN 20-21. Patent Owner argues the claims are patentable for the same reasons that the claims are not obvious in view of Motoyama, Khan '786, and Nazzal. Appeal Br. 33–34. Because we determined that these arguments are unpersuasive, the rejections of claims 4, 11, 12, 21, and 22 are affirmed for the reasons set forth by the Examiner.

TIME PERIOD FOR RESPONSE

In accordance with 37 C.F.R. § 41.79(a)(1), the "[p]arties to the appeal may file a request for rehearing of the decision within one month of the date of: . . . [t]he original decision of the Board under § 41.77(a)." A request for rehearing must be in compliance with 37 C.F.R. § 41.79(b). Comments in opposition to the request and additional requests for rehearing must be in accordance with 37 C.F.R. § 41.79(c), (d), respectively. Under 37 C.F.R. § 41.79(e), the times for requesting rehearing under paragraph (a) of this section, for requesting further rehearing under paragraph (d) of this section, and for submitting comments under paragraph (c) of this section may not be extended.

An appeal to the United States Court of Appeals for the Federal Circuit under 35 U.S.C. §§ 141-144 and 315 and 37 C.F.R. § 1.983 for an *inter partes* reexamination proceeding "commenced" on or after November 2, 2002 may not be taken "until all parties' rights to request rehearing have been exhausted, at which time the decision of the Board is final and appealable by any party to the appeal to the Board." 37 C.F.R. § 41.81. *See also* MPEP § 2682 (8th ed., Rev. 7, July 2008).

In the event neither party files a request for rehearing within the time provided in 37 C.F.R. § 41.79, and this decision becomes final and appealable under 37 C.F.R. § 41.81, a party seeking judicial review must timely serve notice on the Director of the United States Patent and Trademark Office. *See* 37 C.F.R. §§ 90.1 and 1.983.

AFFIRMED

EXHIBIT A

Appeal 2015-007397
Reexamination Control 95/002,396
Patent 8,124,072 B2

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EXHIBIT A