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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/603,807	09/05/2012	Werner Baschong	23264	2439

4743 7590 03/02/2018

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ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
03/02/2018	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte WERNER BASCHONG, OLIVER REICH, and SEBASTIEN MONGIAT[1]

Appeal 2016-001557
Application 13/603,807
Technology Center 1600

Before DEMETRA J. MILLS, TAWEN CHANG, and DEVON ZASTROW NEWMAN, *Administrative Patent Judges*.

CHANG, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to methods for the local treatment or prevention of inflammatory conditions, which have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM, but designate our affirmance as New Grounds of Rejection.

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[1] Appellants identify the real party in interest as CIBA Specialty Chemical Corp. (Br. 3.)

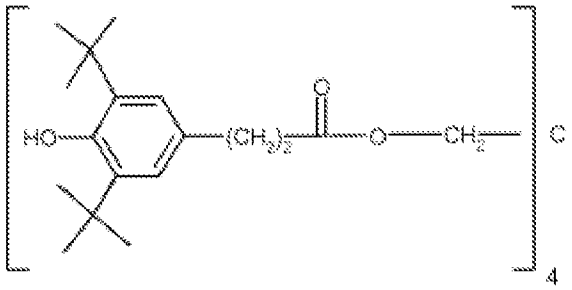
STATEMENT OF THE CASE

According to the Specification, "[i]t is standard practice to use glucocorticoids for the topical treatment of inflammatory and allergic conditions," but "[i]t is common knowledge that these compounds can have unwanted side-effects." (Spec. 1.) Likewise, the Specification states that, "[o]wing to their insufficient ability to penetrate the skin, nonsteroidal anti[-]inflammatory medicaments containing therapeutic agents such as ketoprofen, BW755c, piroxicam, diclofenac or indomethazin cannot effectively be applied topically, but only systemically." (*Id.*)

The Specification states that "some phenol ethers have been proposed having antioxidant, anti-inflammatory and anti[-]allergic properties." (*Id.*) Further according to the Specification, "[i]t is the object of this invention to provide pharmaceutical compositions having surprisingly good pharmacologically properties, in particular antioxidant, anti-inflammatory and anti[-]allergic properties, especially when administered locally." (*Id.*) In particular, the Specification states that the invention relates to the use of carbon or ester/amide bridged phenols or lactones thereof, or some sterically hindered amines, "for the preparation of medicaments or formulations for the treatment of radical induced impairments such as inflammatory or allergic conditions, collagen damages, DNA-damage, or reperfusion-damage (use as anti[-]aging)." (*Id.*)

Claims 1, 7–9, 13, and 14 are on appeal. Claim 1 is representative and reproduced in full in the "CLAIMS APPENDIX" of Appellants' Brief. (Br. 33–43.) In relevant part, claim 1 recites "a method for the local treatment or prevention of inflammatory conditions" comprising "administering to a patient in need of such treatment an effective amount of a pharmaceutical

composition comprising at least one of the . . . compounds of formulae (7) to (35) . . . together with a pharmaceutically acceptable carrier or adjuvant." (Br. 33–42 (Claims App.).) During prosecution, Appellants elected without traverse the following species in response to a restriction requirement:



(Nov. 19, 2012 Response to Restriction Requirement 2; Final Act. 4.)

The Examiner rejects claims 1, 7, 8, 13, and 14[2] under 35 U.S.C. § 103(a) as obvious over Baschong[3] and Pflucker,[4] and the teaching references of Meyer,[5] Brtko,[6] Hersh,[7] FD&C Act,[8] and the entry for "pharmaceutical" in the Merriam-Webster Online Thesaurus.[9] (Final Act. 3.) The Examiner rejects claim 9 under 35 U.S.C. § 103(a) as obvious over

[2] Claim 10 has been cancelled. (Appeal Br. 44 (Claims App.).)
[3] Baschong et al., WO 03/024417 A1, published Mar. 27, 2003 ("Baschong").
[4] Pflucker et al., WO 02/072583 A1, published Sept. 19, 2002 ("Pflucker"). All citations to Pflucker in this decision refers to its U.S. equivalent, Pflucker et al., US 2004/0102446 A1, published May 27, 2004.
[5] Meyer et al., US 7,056,742 B2, issued June 6, 2006 ("Meyer").
[6] J. Brtko et al., *Kojic Acid and Its Derivatives: History and Present State of Art*, 12 CENT. EUROPEAN J. PUB. HEALTH S16 (2004) ("Brtko").
[7] Hersh et al., US 6,337,320 B1, issued Jan. 8, 2002 ("Hersh").
[8] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(g)(1) ("FD&C").
[9] MERRIAM-WEBSTER ONLINE THESAURUS, http://www.merriam-webster.com/thesaurus/phamaceutical (last visited Jun. 29, 2012).

the same set of evidence recited above in combination with Fankhauser.[10] (*Id.* at 10.)

DISCUSSION

Issue

The same issue is dispositive for both of the rejections on appeal. We therefore discuss the rejections together.

The Examiner finds that Baschong discloses pharmaceutical formulations suitable for protecting skin against UV radiation damage, which contain antioxidant light-protective agents in an amount from 0.001 to 30% by weight. (Final Act. 5.) The Examiner finds that Baschong specifically discloses the instantly elected species as one such antioxidant. (*Id.*) The Examiner finds that Baschong also discloses formulations containing water, a "recognized pharmaceutically acceptable carrier." (*Id.*)

The Examiner finds that Hersh teaches that "UV radiation induces skin damage in the form of sunburn, photo[-]aging, and malignancies," that "sunburn includes redness, swelling, and infiltration of the dermal layers by inflammatory cells ([i.e.,] inflammation)," and that "antioxidants in a topical formulation minimize and ameliorate the free radical damage to the skin from UV radiation." (*Id.* at 6.) The Examiner finds that, "[t]hus[,] the prevention of the damaging effect of UV radiation of Baschong is prevention of inflammatory conditions localized to the UV exposed skin" and meets the preamble limitation relating to "local . . . prevention of [an] inflammatory condition[]." (*Id.*)

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[10] Fankhauser, US 2003/0069453 A1, published Apr. 10, 2003 ("Fankhauser").

In the alternative, the Examiner finds that the preamble limitation relating to "local treatment or prevention of inflammatory conditions" is an intended use that does not patentably distinguish the claimed invention over the prior art. (*Id.* at 8.) In particular, the Examiner finds that

> Baschong discloses the identical pharmaceutical antioxidant composition as instantly claimed . . . in the concentration which completely overlaps the claimed concentration . . . . Because both the composition and concentration of Baschong and in this instant application are the same, it would be expected that the composition would have the same inherent property, mainly the treatment or prevention of inflammatory skin damage.

(*Id.*)

The Examiner finds that Baschong does not specifically disclose "the method step of administering to a patient in need of . . . treatment [of inflammatory conditions] an effective amount of [the elected] compound." (*Id.* at 7.) However, the Examiner finds that Pflucker discloses applying to the skin and hair an effective amount of a compound for protecting against UV radiation, and further finds that, "as all people are [affected by] the influences of sunlight and the harm of UV exposure any person would be a patient in need . . . [of] the prevention and treatment [of inflammatory conditions]." (*Id.* at 8.)

The Examiner concludes that it would have been obvious to combine the teachings of Baschong and Pflucker to arrive at the claimed invention, with a reasonable expectation of success, because Baschong discloses that "an antioxidant [that] can be used for UV protection can be used as part of a topical skin cream" and "the standard method for using a topical composition is to apply it to the skin as disclosed by Pflucker." (*Id.* at 9.)

Appellants contend that the cited references do not suggest a method for the local treatment or prevention of ***inflammatory conditions*** or the step of administering the recited pharmaceutical composition to ***a patient in need of such treatment***. (Br. 17–18.)

The issues with respect to this rejection are:

1. Whether the preamble of claim 1 recites an "intended use" that does not patentably distinguish over the prior art;

2. If the preamble is limiting, whether a preponderance of evidence of record supports the Examiner's finding that the combination of cited art renders obvious "[a] method for the local treatment or prevention of inflammatory conditions comprising: administering to a patient in need of such treatment . . . a . . . composition comprising [the elected compound]."

Findings of Fact

1. Baschong teaches "compositions comprising (a) (-)-guaiol, (b) further skin-lightening active substance(s) and, optionally, (c) one or more UV-A and/or UV-B absorbers as melanogenesis inhibitors and for skin-lightening." (Baschong, Abstract.)

2. Baschong teaches that its compositions are "suitable for protecting ultraviolet-sensitive organic materials, especially the skin, against the damaging effect of UV radiation, especially for lightening the skin in conjunction with one or more UV filter(s), that is to say during or after simultaneous lightening of the skin." (*Id.* at 18.)

3. Baschong teaches that,

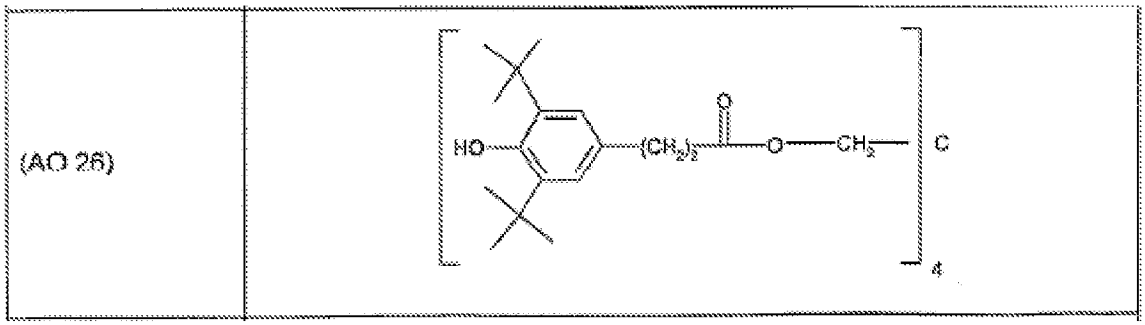
> [i]n the compositions according to the invention, it is also possible to use, in addition to components (a), (b) and (c), secondary light-protective agents of the antioxidant kind which interrupt the photochemical reaction chain triggered when UV

> radiation penetrates the skin or hair. That property is desirable for cosmetic light protection because, as a result of the influence of UV and light, damaging radicals may be formed both in formulations and on the skin. Providing the compositions according to the invention with antioxidants achieves not only protection from UV damage but also, at the same time, protection from the photochemical degradation of constituents in the formulation.

(*Id.* at 28.)

4. Baschong teaches that typical examples of antioxidants that interrupt the photochemical reaction chain triggered when UV radiation penetrates the skin or hair include, e.g., selenium and derivatives thereof and thiols such as glutathione. (*Id.* at 28–29.)

5. Baschong teaches that "[m]ention may also be made of [certain] phenolic antioxidants," including the compound having the following chemical structure:



(*Id.* at 29, 35.) The chemical structure reproduced above is labeled as compound (AO26) in Baschong and is the elected compound in the application on appeal. (*Id.*; Nov. 19, 2012 Response to Restriction Requirement 2; Final Act. 4.)

6. Baschong teaches that "[t]he amounts of antioxidants is usually from 0.001 to 30 % by weight, preferably from 0.01 to 3 % by weight, based

on the weight of the composition according to the invention." (Baschong 38.)

7. Baschong teaches that its formulation may "exist in a wide variety of presentation forms," including gels, creams, and pastes, which thus suggests topical application of the formulation. (*Id.* at 42.)

8. Hersh teaches:

> the combination of several anti-oxidants, including enzymatic co-factors and thiol compounds, and various tissue and cell growth stimulating factors . . . as a means of both minimizing and ameliorating and also concomitantly repairing free radical damage to the skin from ultraviolet radiation and also stimulating the growth, differentiation and maturation of epidermal cells resulting from environmental and metabolic factors.

(Hersh 1:5–13; *see also id.* at 7:3–12, 7:22–24, 10:30–40.)

9. In particular, Hersh teaches "[a] composition of L-glutathione (reduced) and selenium and an epidermal growth factor . . . and method of using the composition to reduce and repair ultraviolet radiation-induced skin damage, both acute injury (sunburn) and chronic damage (photo[-]aging and cutaneous malignancies)." (*Id.* at Abstract; *see also id.* at 7:24–27, 7:40–45, 7:56–66.)

10. Hersh teaches that sunscreens alone are not adequate in protecting skin from UV radiation or in repairing skin damaged by UV radiation. (*Id.* at 5:27–29.)

11. Hersh teaches that

> [i]t is important to supply locally both glutathione and the synergistic antioxidants to restore epidermal glutathione levels and enhance the reparative antioxidant chain breaking reactions. It becomes imperative to prevent UV ray damage by prophylaxis with skin care (sun protection) products and

> appropriate clothing, plus the prevention of free radicals and their neutralization by locally applied chain-breaking antioxidant preparations, as proposed in the present application.

(*Id.* at 12:42–49; *see also id.* at 20:43–47, 24:15–17 (teaching that "sunburn should be treated with the combination of synergistic endogenous and exogenous antioxidants as outlined herein").)

12. Hersh teaches that sunburn involves an inflammatory response. (*Id.* at 1:64–2:3, 4:55–5:6.)

13. Hersh teaches the topical administration of its composition to human skin. (*Id.* at 11:51–54; *see also id.* at Abstract, 1:5–13, 7:45–66, 10:30–37.)

14. Pflucker teaches "use of quinoxaline derivatives as photostable UV filters in cosmetic and pharmaceutical preparations for protection of the human epidermis or human hair against UV radiation, especially in the range 280-400 m." (Pflucker ¶ 1.)

15. Pflucker also teaches "a method for protecting the skin and . . . hair against solar radiation, in which an effective amount of [the inventive compound] in a cosmetic preparation is applied to the skin or the hair." (*Id.* ¶ 135; *see also id.* ¶ 178 (topical administration), ¶ 222 (sunscreen spray), ¶ 236 (sunscreen gel), ¶¶ 250, 262 (sunscreen lotion).)

16. Pflucker teaches that

> [i]t is furthermore possible and advantageous to combine the preparations according to the invention with antioxidants. A combination of this type then exhibits both a protective action as antioxidant and also against burns due to UV radiation. A protective action against oxidative stress or against the action of free radicals can thus also be achieved.

(*Id.* ¶ 132; *see also id.* ¶¶ 164–166.)

Analysis

We find the preamble "[a] method for the local treatment or prevention of inflammatory conditions" to be limiting; however, we agree with the Examiner that the cited prior art combination suggests such a method comprising "administering to a patient in need of such treatment . . . a . . . composition comprising [the elected compound]."

With respect to whether the preamble is limiting, our reviewing court has held that,

> [i]f a preamble "recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim," then the preamble can limit the scope of a claim. *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (citation omitted). "Conversely, a preamble is not limiting 'where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.'" *Id.* (quoting *Rowe v. Dror*, 112 F.3d 473, 478 (Fed.Cir.1997)). "'[W]hether to treat a preamble as a claim limitation is determined on the facts of each case in light of the claim as a whole and the invention described in the patent.'" *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 952 (Fed. Cir. 2006) (quoting *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 831 (Fed. Cir. 2003)).

TomTom, Inc. v. Adolph, 790 F.3d 1315, 1323 (Fed. Cir. 2015). In this case, we find the preamble to be limiting because it acts as an antecedent basis for a phrase in the body of the claim: that is, the step of "administering to a patient in need of ***such treatment***" refers to the phrase in the preamble relating to "local treatment . . . of inflammatory conditions." *Catalina Mktg.*, 289 F.3d at 808 (explaining that "dependence on a particular disputed preamble phrase for antecedent basis may limit claim scope because it indicates a reliance on both the preamble and claim body to define the claimed invention").

Although we find the preamble to be limiting, we nevertheless agree with the Examiner that the cited prior art combination renders obvious "[a] method for the local treatment or prevention of inflammatory conditions comprising: administering to a patient in need of such treatment . . . a . . . composition comprising [the elected compound]." (Appeal Br. 33 (Claims App.).) Specifically, Baschong teaches that the elected compound is an antioxidant suitable for use in a composition "for protecting skin against UV radiation damage" as "secondary light-protective agents" that achieves UV protection by "interrupt[ing] the photochemical reaction chain triggered when UV radiation penetrates the skin or hair." (FF2, FF3.) Hersh similarly suggests that a composition comprising a combination of antioxidants such as L-glutathione (reduced) and selenium reduce and repair UV-induced skin damage, including acute damage such as sunburn, through "reparative antioxidant chain breaking reactions." (FF8, FF9, FF11.) Hersh further teaches that sunburn involves an inflammatory response. (FF12.)

Given the teachings of Baschong and Hersh, we find that it would be obvious for a skilled artisan to administer a composition comprising the elected compound to a patient in need of treatment for sunburn, an inflammatory condition: Baschong teaches that the elected compound is an antioxidant that acts as a "light-protective agent" by "interrupt[ing] the photochemical reaction chain triggered when UV radiation penetrates the skin or hair" (FF3–FF5), while Hersh teaches that other antioxidants functioning in similar fashion is useful in reducing and repairing skin damage such as sunburn (FF8, FF9, FF11). As for the limitation regarding local treatment, we note that both Baschong and Hersh teach or suggest topical application of their compositions, while Pflucker, a reference that

also teaches cosmetic and pharmaceutical preparations protecting against UV radiation, likewise teaches topical application of its preparations to skin or hair. (FF7, FF13, FF15.)

Appellants contend that Baschong teaches using guaiol in mixtures with other components to lighten or prevent tanning of the skin and does not suggest a method for the treatment or prevention of inflammatory conditions. (Br. 17–19.) While Appellants concede that Baschong discloses the elected compound as a phenolic antioxidant, Appellants argue that Baschong teaches that such antioxidants are optional, that even if an antioxidant such as the elected compound is added to Baschong's formulation, the formulation is still "specifically designed to lighten" or prevent the tanning of skin, and that "Baschong's teaching that the antioxidants can interrupt the photochemical reaction chain triggered when UV radiation penetrates the skin or hair is not the same as or similar to a method of preventing or treating inflammation conditions." (*Id.* at 23.)

We are not persuaded. "A reference may be read for all that it teaches, including uses beyond its primary purpose." *In re Mouttet*, 686 F.3d 1322, 1331 (Fed. Cir. 2012). Thus, the fact that Baschong primarily teaches a composition for lightening or preventing tanning of the skin and teaches the elected compound as an optional ingredient does not diminish the relevance of its teaching with respect to the use of the elected compound. Likewise, while Baschong's teaching that antioxidants such as the elected compound interrupts the photochemical reaction chain triggered by penetration of UV radiation in skin and hair does not by itself suggest a method of preventing or treating inflammatory conditions, it renders such a method obvious when combined with Hersh's teaching that antioxidants

performing a similar function are useful in treating sunburn, an inflammatory condition.

Appellants acknowledge that Hersh discusses sunburn, an inflammatory condition, as one possible damaging effect of UV radiation. (Br. 20.) However, Appellants contend that "it is well known . . . that there are a multitude of different effects that can be caused by UV radiation," and Baschong focuses on a tanning effect of UV radiation that is not the same or similar to sunburn. (*Id.*) We are not persuaded for the same reasons already discussed. In particular, Hersh does not merely discuss sunburn as a possible damaging effect of UV radiation, but also teaches using a combination of antioxidants that enhance reparative antioxidant chain breaking reactions to treat sunburn. (FF8, FF9, FF11.) This teaching combined with Baschong's teaching of the elected compound as an antioxidant that interrupts the photochemical reaction chain triggered by UV radiation in skin or hair would have rendered it obvious to use the elected compound in treating sunburn, as discussed above

Appellants contend that the Examiner's citation to the FD&C Act and Merriam-Webster to show that "the[] components of Baschong's cosmetic formulations may qualify as drugs or fall under the FDA category of mitigate, treat or prevent a disease" does not cure the defects in the rejection, because "[such] teaching is not equivalent to a teaching of local treatment or prevention of *inflammatory conditions*." (Br. 22.) While we agree that the FD&C Act and Merriam Webster does not suggest that the elected compound may be used to treat or prevent an inflammatory condition, the Examiner cites these references only to show that the prior art combination

suggests a pharmaceutical composition rather than merely a cosmetic composition, a point Appellants have not disputed. (Final Act. 6–7.)

Appellants further argue that Baschong also fails to suggest the step of "administering to a patient in need of . . . treatment an effective amount of a pharmaceutical composition." (Br. 24.) Appellants contend that the Examiner's citation to Pflucker does not cure this deficiency in Baschong because "it would not be obvious for one of ordinary skill in the art to turn to Pflucker after reading Baschong seeking a method step of administering the formulation to a patient in need when the active components of the formulation[s] are completely different." (*Id.* at 25.) Appellants further disagree with the Examiner's position that, "'as all people are [a]ffected [by] the influences of sunlight and the harm of UV exposure any person would be a patient in need thereof for the prevention and treatment.'" (*Id.* at 26–27 (citing Final Act. 8).)

We agree with Appellants that not every person would meet the claim limitation of "a patient in need of [local] treatment [of inflammatory conditions." In *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1378–79 (Fed. Cir. 2005), the Federal Circuit held that prior art disclosure of the topical application of a lotion does not anticipate a claim specifically reciting application of the lotion to skin sunburn, because "[t]he issue is not . . . whether [the] lotion *if applied* to skin sunburn would inherently treat that damage[] but whether [the prior art] discloses the application of its composition to skin sunburn." Similarly, not every person is in need of treatment for inflammatory conditions because not every person suffers

from, e.g., sunburn.[11] Nevertheless, as discussed above, we find that the cited prior art combination suggests administration of the elected compound to a patient in need of treatment of an inflammatory condition (i.e., sunburn), because Hersh suggests that antioxidant chain breaking reactions help to repair UV radiation-induced damage such as sunburn, and Baschong teaches that the elected compound is an antioxidant that interrupts the undesirable photochemical reaction chain triggered by UV radiation. Thus, unlike in *Perricone*, the cited prior art combination suggests the application of the elected compound to skin sunburn.

Finally, for the same reasons as discussed above, we note but are not persuaded by Appellants' argument that the rejection of claim 1 relies on impermissible hindsight. (Appeal Br. 28.) "Any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971).

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[11] The Federal Circuit in *Perricone* held that a prior art's disclosure of the topical application of the claimed composition necessarily anticipates a claim to a method of preventing skin sunburn, because while not all skin suffers from sunburn, "all skin surfaces are susceptible to sunburn damage." *Perricone*, 423 F.3d at 1379. However, we note that the claim on appeal does not recite administering to a patient in need of treatment ***or prevention*** of inflammatory conditions such as sunburn. Thus, we do not address whether topical administration of Baschong's composition would inherently meet the limitation of "administering to a patient in need of" treatment ***or prevention*** of inflammatory conditions.

Accordingly, we affirm the Examiner's rejection of claim 1. Claims 7, 8, 13, and 14, which were not separately argued, fall with claim 1. *See* Br. 16; 37 C.F.R. § 41.37(c)(1)(iv). Appellants do not make any separate or additional arguments with respect to claim 9; thus, we affirm the rejection of claim 9 for the same reasons. Because our reasoning differs from that of the Examiner, however, we designate our affirmance as New Grounds of Rejection to provide Appellants with an opportunity to respond.

SUMMARY

For the reasons above, we affirm the Examiner's decision rejecting claims 1, 7–9, 13, and 14 but designate our affirmance as new grounds of rejection.

TIME PERIOD FOR RESPONSE

This decision contains new grounds of rejection pursuant to 37 C.F.R. § 41.50(b). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that Appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new grounds of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new Evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the prosecution will be remanded to the examiner. . . .
> (2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same Record. . . .

Further guidance on responding to a new ground of rejection can be found in the Manual of Patent Examining Procedure § 1214.01

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED; 37 C.F.R. § 41.50(b)