

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte

ROBERT T. LYONS and ROBERT S. JORDAN

Appeal 2008-3450
Application 10/865,639
Technology Center 1600

Decided: November 14, 2008

Before DONALD E. ADAMS, ERIC GRIMES, and MELANIE L.
McCOLLUM, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an ophthalmic composition. The Examiner has rejected the claims as indefinite, lacking written description support, and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse the indefiniteness and written description rejections and affirm the obviousness rejection.

STATEMENT OF THE CASE

Claims 1-20 are pending and on appeal. We will focus on claims 1, 6, and 16, which are representative and read as follows:

1. An ophthalmic composition comprising an effective amount of a therapeutically active agent having an oxidizable functional group, an effective amount of stabilized chlorine dioxide to act as a preservative, and an effective amount of citric acid and/or conjugate bases thereof to stabilize said therapeutically active agent in the presence of said stabilized chlorine dioxide.

6. The composition of claim 1 comprising a borate/boric acid buffer.

16. A method of preserving an ophthalmic composition comprising providing an effective amount of citric acid and/or conjugate bases thereof and stabilized chlorine dioxide to said composition.

Claims 6, 10, and 17-20 stand rejected under 35 U.S.C. § 112, second paragraph (Ans. 3).

Claims 1-20 stand rejected under 35 U.S.C. § 112, first paragraph, “as failing to comply with the written description requirement” (*id.*).

Claims 1-20 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Kararli (US 2002/0035264 A1, Mar. 21, 2002) and Ripley (US 5,736,165, Apr. 7, 1998) (*id.* at 5).

INDEFINITENESS

Claims 6, 10, and 17-20 stand rejected under 35 U.S.C. § 112, second paragraph. The Examiner finds that there is insufficient antecedent basis for “the limitation ‘a borate/boric acid buffer . . .’” (Ans. 3). In particular, the Examiner argues that “[c]laims 1 and 8 are limited to certain ingredients and have no basis for the limitations appellant has recited in claims [6], 10, 17, 18, 19 and 20” (*id.* at 7).

Appellants argue that the “claims are sufficiently clear for a person of ordinary skill to ‘reasonably ascertain’ their scope” (App. Br. 6).

Issue

Did the Examiner err in concluding that phrases in dependent claims that do not have antecedent basis in the claims on which they depend made these dependent claims indefinite?

Findings of Fact

1. Claim 1 is directed to an ophthalmic composition “comprising” a therapeutically active agent, stabilized chlorine dioxide, and citric acid and/or conjugate bases thereof.

2. Claim 1 does not recite that the composition comprises a borate/boric acid buffer.

3. Claim 6 depends from claim 1 and recites that the composition comprises “a borate/boric acid buffer.”

Analysis

“A claim is indefinite if its legal scope is not clear enough that a person of ordinary skill in the art could determine whether a particular composition infringes or not.” *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003). We agree with Appellants that the Examiner has not shown that the claims rejected on this basis are indefinite.

Claim 1 recites a composition “comprising” various components (Finding of Fact (FF) 1). Based on the “comprising” language, claim 1 is open to the inclusion of additional components. *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997) (“‘Comprising’ is a term of art

used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.”).

Claim 6 recites that the composition comprises “a borate/boric acid buffer” (FF 3). The recitation of “a borate/boric acid buffer” does not have antecedent basis in claim 1, on which claim 6 depends (FF 2-3). However, as noted by Appellants (App. Br. 6), the phrase “borate/boric acid buffer” is not directly preceded by the terms “the” or “said” (FF 3), which often indicates that a phrase refers to a previously recited element, and therefore requires antecedent basis in another claim or earlier in the same claim.

We do not agree that the failure of the phrase “a borate/boric acid buffer” to have antecedent basis in claim 1 makes claim 6 indefinite. Instead, claim 6 clearly requires that the composition includes “a borate/boric acid buffer.” The composition can include “a borate/boric acid buffer” in addition to the components recited in claim 1 or, if “a borate/boric acid buffer” can constitute one of the components recited in claim 1, the composition can include “a borate/boric acid buffer” as one of the components recited in claim 1. That claim 6 does not specify whether the borate/boric acid buffer is one of the constituents recited in claim 1 or is an additional component does not make this claim indefinite.

We therefore reverse the indefiniteness rejection of claim 6. For substantially the same reasons, we reverse the indefiniteness rejection of claims 10 and 17-20.

WRITTEN DESCRIPTION

Claims 1-20 stand rejected under 35 U.S.C. § 112, first paragraph, “as failing to comply with the written description requirement” (Ans. 3). The Examiner finds that the “claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention” (*id.*). In particular, the Examiner finds:

[T]he instant specification fails to provide an adequate written description of suitable therapeutically active agents having an oxidizable functional group. The specification describes only a limited number of such agents. The instant claims generally recite “a therapeutically active agent having an oxidizable functional group”. When functional groups are drawn this broadly, they are inclusive of any therapeutically active agents, which can be small molecules, peptides, peptide mimetics or RNA-DNA based structures. The instant specification quite simply discloses a few compounds within the scope of the claimed language. As such, it cannot provide any direction for using any peptides, peptide mimetics, or RNA-DNA based structure, no identifying characteristics of any kind, e.g. sequences are provided. Accordingly the instant specification fails to provide an adequate written description.

(*Id.* at 4.)

Appellants argue that, “[a]t the time of filing, therapeutically active agents were known in the art, and many therapeutically active agents of known structure were currently being used to treat conditions afflicting people” (App. Br. 9).

Appellants also argue that the Examiner did not even explain why some of the claims that are rejected on this basis are not supported by an adequate written description (*id.* at 5).

Issues

Did the Examiner err in concluding that the claim recitation of a “therapeutically active agent” is not supported by an adequate written description? In addition, did the Examiner set forth a prima facie case that claims that do not even require a therapeutically active agent are not supported by an adequate written description?

Findings of Fact

4. The Specification discloses an “ophthalmic composition comprising an effective amount of a therapeutically active agent, stabilized chlorine dioxide, and citric acid and/or conjugate bases thereof” (Spec. 2: 12-14).

5. The Specification discloses that, “if stabilized chlorine dioxide is in a composition with certain therapeutically active agents, either the stabilized chlorine dioxide, or the therapeutically active agent, or both, are unstable,” but that “[s]urprisingly, citric acid and/or conjugate bases thereof have been discovered to improve the stability of these combinations” (*id.* at 3: 5-11).

6. In the Specification, “therapeutically active agent” is defined as “a compound or compounds which are used to treat or prevent any disease or undesirable condition which afflicts an animal” (*id.* at 3: 12-15).

7. The Specification also discloses that, “[i]n one embodiment, the therapeutically active agent . . . is bimatoprost” (*id.* at 5: 24-25).

8. In addition, the Specification discloses that “it is generally believed in the art that oxidation reactions are generally nonselective reactions[. Therefore], the fact that stabilized chlorine dioxide destabilizes bimatoprost suggests that a broad variety of compounds will be oxidized by chlorine dioxide.” (*Id.* at 5: 26-29.)

9. The Specification also discloses a “therapeutically active agent compris[ing] a carboxylic acid, a carboxylic acid ester, or a carboxylic acid amide” (*id.* at 6: 11-12). Specifically, the Specification discloses that “the therapeutically active agent is a prostaglandin or prostamide such as bimatoprost, latanoprost, travoprost, unoprostone isopropyl, and the like, which have carboxylic acid, ester, or amide groups” (*id.* at 6: 12-15). In addition, the Specification discloses a therapeutically active agent comprising a sulfur atom (*id.* at 6: 15-16). The Specification also discloses that “[o]ther functional groups that may be susceptible to stabilized chlorine dioxide are amines, phenols, alcohols, aromatic amino acids, non-conjugated double bonds, and similar groups” (*id.* at 6: 16-19).

10. Therapeutically active agents having an oxidizable functional group, including bimatoprost, were known in the art at the time of Appellants’ invention (Kararli ¶¶ [0003]-[0011] & [0350]).

Analysis

The first paragraph of 35 U.S.C. § 112 “requires a ‘written description of the invention.’” *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). To comply with the written description requirement, the Specification must “convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [the inventor] was in possession of the

invention.” *Id.* at 1563-64. In addition, “[t]he ‘written description’ requirement must be applied in the context of the particular invention and the state of the knowledge. . . . As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.” *Capon v. Eshhar*, 418 F.3d 1349, 1358 (Fed. Cir. 2005).

Appellants’ Specification discloses an “ophthalmic composition comprising an effective amount of a therapeutically active agent, stabilized chlorine dioxide, and citric acid and/or conjugate bases thereof” (FF 4). In addition, the Specification defines “therapeutically active agent” and provides examples of therapeutically active agents having an oxidizable functional group, such as bimatoprost (FF 6-7 & 9). Therapeutically active agents having an oxidizable functional group, including bimatoprost, were known in the art at the time of Appellants’ invention (FF 10). Therefore, we agree with Appellants that their Specification need not disclose the therapeutically active agents in additional detail. *Cf. Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) (“a patent need not teach, and preferably omits, what is well known in the art”). As a result, we agree with Appellants that the Examiner has not set forth a prima facie case that claim 1 is not supported by an adequate written description.

We therefore reverse the written description rejection of claim 1 and of claims 2-10 and 17-20, which depend from claim 1. For substantially the same reasons, we reverse the written description rejection of claim 12 and of claims 13-15, which depend from claim 12.

With regard to claims 11 and 16, we note that these claims do not recite a “therapeutically active agent.” As a result, the Examiner’s basis for rejecting claim 1 does not even apply to these claims. Therefore, we also reverse the written description rejection of these claims.

OBVIOUSNESS

Claims 1-20 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Kararli and Ripley. The claims have not been argued separately and therefore stand or fall together.¹ 37 C.F.R. § 41.37(c)(1)(vii). We will focus on claim 16.

The Examiner relies on Kararli for teaching “a composition of an active agent having a sulfur or a carboxylic acid, which can be used in combination with chlorine dioxide as a preservative and citric acid as a buffering agent” (Ans. 8). The Examiner also finds that Kararli teaches the use of bimatoprost (*id.* at 6).

The Examiner relies on Ripley for teaching that “stabilized chlorine dioxide is considered to be a chlorine dioxide precursor” (*id.*). The Examiner finds that Ripley “makes clear that chlorine dioxide is an effective ophthalmic preservative and the addition of citric acid to chlorine dioxide in

¹ In the Reply Brief, Appellants argue that, “[f]or the dependent claims, Examiner did even less, she merely pointed out roughly where some of the compounds found in the dependent claims were located in the references without any additional explanation. This is not a proper way to make an obviousness rejection.” (Reply Br. 10.) In addition to being untimely raised for the first time in the Reply Brief, this argument does not point out why any claim is separately patentable and therefore does not comply with 37 C.F.R. § 41.37(c)(1)(vii). Therefore, we have not separately considered the dependent claims.

ophthalmic formulations is old and well known” (*id.*). The Examiner concludes that it would have been obvious “to add citric acid to chlorine dioxide” (*id.*).

Appellants contend that Kararli does not provide any motivation to combine its various teachings, that Ripley teaches away from the claimed combination, and that the claimed combination provides unexpectedly superior results (App. Br. 3-5; Reply Br. 4-10).

Issues

Have Appellants shown that the Examiner did not set forth a prima facie case that claim 16 would have been obvious and, if not, have Appellants provided sufficient evidence to rebut the prima facie case of obviousness?

Findings of Fact

11. Kararli discloses “a pharmaceutical composition suitable for topical administration to an eye . . . compris[ing] a selective COX-2 inhibitory drug” (Kararli ¶ [0065]).

12. Kararli also discloses including “[o]ne or more ophthalmically acceptable pH adjusting agents and/or buffering agents . . . , including acids such as acetic, boric, [and] citric . . . acids; [and] bases such as . . . sodium borate [and] sodium citrate. . . .” (*Id.* at ¶ [0341].)

13. In addition, Kararli discloses including “one or more ophthalmically acceptable preservatives . . . to inhibit microbial activity. Suitable preservatives include . . . stabilized chlorine dioxide. . . .” (*Id.* at ¶ [0345].)

14. Kararli also discloses using “[a]ny drug having utility as a topical ophthalmic application . . . in co-therapy, co-administration or co-formulation with a composition of the invention. . . . Such drugs include . . . bimatoprost.” (*Id.* at [0350].)

15. Ripley discloses using “chlorine dioxide-containing compositions in the eye” (Ripley, col. 1, ll. 66-67).

16. In particular, Ripley discloses that “[s]uch compositions have been found to be effective as ophthalmic antiseptics or ophthalmic surgical irrigants” (*id.* at col. 3, ll. 1-2).

17. Ripley also discloses that the “compositions preferably have a pH in the range of about 6 to about 10. . . . Effective amounts of buffer components . . . may be included to provide that such compositions have the desired pH values.” (*Id.* at col. 3, ll. 50-55, & col. 4, ll. 25-35.)

18. In addition, Ripley discloses “producing the chlorine dioxide-containing compositions from precursor compositions including chlorine dioxide precursor components” (*id.* at col. 4, ll. 51-54).

19. Ripley identifies stabilized chlorine dioxide as a chlorine dioxide precursor and identifies Purogene[®] as an especially useful stabilized chlorine dioxide (*id.* at col. 5, ll. 23-36).

20. Ripley also discloses that the composition “is substantially free of any activator (or other) component . . . used to promote, e.g., activate, the production of chlorine dioxide from the chlorine dioxide precursor component” (*id.* at col. 5, l. 65, to col. 6, l. 3).

21. However, Ripley discloses that an “activator component may be employed to effect the generation of chlorine dioxide from the . . . chlorine dioxide precursor components” (*id.* at col. 5, ll. 55-57).

22. Ripley also discloses that, “[a]t mildly acidic conditions, in particular at a pH of less than about 6 and especially in the range of about 3 to about 5, the production of chlorine dioxide is effected from the chlorine dioxide precursors” (*id.* at col. 6, ll. 16-19).

23. Thus, Ripley discloses employing “[a]ny suitable acidic component . . . as the activator component” (*id.* at col. 6, ll. 19-20).

24. Ripley also discloses that “[s]uch acidic components should . . . have no substantial detrimental effect on the eye or ocular tissue being cared for or irrigated” (*id.* at col. 6, ll. 27-29).

25. In addition, Ripley discloses that “[e]xamples of the presently useful acidic components include . . . citric acid. . . .” (*Id.* at col. 6, ll. 30-33.)

26. Ripley also discloses that, “[d]uring chlorine dioxide generation using acid activation, it is preferred that the liquid aqueous medium have a pH of about 6 or less. . . . The amount of acidic component employed is preferably sufficient to provide the precursor-containing liquid medium with the desired pH.” (*Id.* at col. 6, ll. 45-51.)

27. In addition, Ripley exemplifies adding a stabilized chlorine dioxide product to a borate-buffered saline solution. Ripley states that the “resulting solution has a pH of about 7.3 . . . and is ophthalmically acceptable.” (*Id.* at col. 8, ll. 56-67.)

28. The Specification, in Example 3, discloses the preparation of the following compositions D and E:

Table 4. Composition of Bimatoprost With and Without Citric Acid

Ingredient	Concentration (% w/w)	
	D	E
Bimatoprost	0.03	0.03
Purite [®]	0.005	0.005
Citric Acid	0.014	-
Boric Acid	0.60	0.60
Sodium Borate	0.045	0.045
Sodium Chloride	0.39	0.39
Carboxymethylcellulose	0.50	0.50
HCl/NaOH	pH to 7.3	pH to 7.3
Purified Water	q.s. 100%	q.s. 100%

(Spec. 10: 14 to 11: 8).

29. Compositions D and E each contain bimatoprost and Purite[®], which are identified in the Specification as a therapeutically active agent and a stabilized chlorine dioxide, respectively (*id.* at 5: 24-25 & 3: 27-30). Composition D also contains citric acid, whereas composition E does not. (*Id.* at 11: Table 4.)

30. The Specification discloses that compositions D and E “were stored at 50°C and the concentrations of bimatoprost (Figure 1) and Purite[®] (Figure 2) were determined at 3, 6 and 10 weeks” (*id.* at 10: 19-20).

31. Specification Figures 1 and 2 show a recovery of a greater percent of the bimatoprost and the Purite[®] after storage at 3, 6, and 10 weeks from the composition containing citrate as compared to the composition that did not contain citrate (*id.* at Fig. 1-2).

Analysis

Under 35 U.S.C. § 103, “the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are

to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.” *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

Claim 16 is directed to a “method of preserving an ophthalmic composition comprising providing an effective amount of citric acid and/or conjugate bases thereof and stabilized chlorine dioxide to said composition.” Kararli discloses including stabilized chlorine dioxide in an ophthalmic composition as a preservative (FF 13). Kararli also discloses including in the composition “[o]ne or more ophthalmically acceptable pH adjusting agents and/or buffering agents,” such as citric acid or sodium citrate (FF 12). In addition, Ripley discloses ophthalmic compositions including stabilized chlorine dioxide and a buffer and states that citric acid has “no substantial detrimental effect on the eye or ocular tissue” (FF 15-19, 24-25, & 27). As discussed further below, we agree with the Examiner that the disclosures of Kararli and Ripley provide a prima facie case that the method of claim 16 would have been obvious.

Appellants argue that the “Examiner pulled the words citrate and stabilized chlorine dioxide from two different extensive laundry lists” and that this “does not establish prima facie obviousness” (App. Br. 3-4). In particular, Appellants argue that the “MPEP (and the case law from which it draws) requires that at the very least, the Kara[r]li reference provide a suggestion or motivation to combine the reference teachings” and that Kararli “does not provide such a suggestion or motivation” (*id.* at 4). Specifically, Appellants argue:

The [Kararli] specification lists 11 “preferred,” “particular,” “particularly preferred,” or otherwise designated compositions

in the specification; 1 example; 40 claims; and one abstract. This represents 52 opportunities to provide a motivation or suggestion to combine the reference teachings. None of these mentions or suggests the combination, and Examiner has not provided a single suggestion or motivation from the reference to make the required combination.

(*Id.*)

We are not persuaded. As noted by Appellants, Kararli discloses a list of ophthalmically acceptable pH adjusting agents and/or buffering agents and a list of ophthalmically acceptable preservatives (FF 12-13). However, in view of the limited number of members on each of these lists, we agree with the Examiner that it would have been *prima facie* obvious to combine any of these pH adjusting and/or buffering agents with any of these preservatives. “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007).

Appellants also argue that Ripley “*teaches away* from the claimed composition” (App. Br. 4). In particular, Appellants argue that Ripley teaches:

[C]itric acid is an *activator* . . . , meaning that it frees the chlorine dioxide from its stabilizing complex. Stabilized chlorine dioxide is referred to as “*stabilized*” because it is more stable than the free chlorine dioxide, which is a strong oxidant and notoriously unstable. Thus, freeing chlorine dioxide from its stabilizing complex does not stabilize chlorine dioxide at all, but makes it less stable, i.e. more reactive. . . . If a person of ordinary skill is faced with an instability problem in combining stabilized chlorine dioxide and an oxidatively unstable therapeutically active agent in a single composition, she will certainly not add a compound which activates chlorine dioxide. This would cause even more oxidation of the therapeutically

active compound and quicker degradation of the stabilized chlorine dioxide.

(Id.)

We are not persuaded. Claim 16 does not require adding acid to the composition. Instead, claim 16 encompasses adding citric acid and/or conjugate bases thereof. Thus, claim 16 does not require that the composition be made more acidic. In particular, claim 16 does not require that sufficient acid be added to activate the stabilized chlorine dioxide (*see* FF 22 & 26). Thus, we do not agree that Ripley teaches away from the claimed combination. In fact, Ripley exemplifies a composition containing a stabilized chlorine dioxide and a buffer (FF 27). Although the buffer in this example is not a citric acid/citrate buffer, Ripley clearly provides further evidence that it was known in the art to combine stabilized chlorine dioxide with a buffer. In addition, Ripley provides further evidence that citric acid was known to be used in ophthalmic compositions (FF 24-25), providing further evidence that it would have been obvious to use citric acid and a conjugate base thereof as a buffer in an ophthalmic composition.

In addition, Appellants argue:

In order to arrive at the claimed invention from the prior art, a person of ordinary skill must make four distinct selections. First, a person of ordinary skill in the art must choose a therapeutically active agent from Kararli, or some other component that is unstable in the presence of stabilized chlorine dioxide from Kararli or Ripley. Second, the person must choose chlorine dioxide as the preservative. Third, the person must recognize that the two are unstable in one another's presence. Fourth, the person must decide to use citric acid in an effective amount to stabilize the two. This decision must be made despite the facts that: 1) Ripley teaches that citric acid

activates stabilized chlorine dioxide, and 2) Kararli discloses antioxidants for stabilizing chemical compounds and teaches ascorbic acid and sodium metabisulfite, but not citrate, as antioxidants.

(Reply Br. 7-8.) Appellants argue that this “relationship is far to[o] attenuated for the claimed invention to be obvious from the prior art” (*id.* at 8).

We are not persuaded. First, claim 16 does not recite that the composition contains a therapeutically active agent or another component that is unstable in the presence of stabilized chlorine dioxide. Second, we do not agree that one of ordinary skill in the art would need to recognize that two compounds are unstable in one another’s presence or use citric acid to stabilize the two. In establishing a prima facie case of obviousness, the prior art does not have to teach combining reference teachings for the reason that Appellants combined them. *Cf. In re Dillon*, 919 F.2d 688, 692-93 (Fed. Cir. 1990) (en banc). Furthermore, for the reasons discussed above, we agree with the Examiner that it would have been prima facie obvious to combine any of Kararli’s pH adjusting and/or buffering agents, including citric acid and/or conjugate bases thereof, with any of Kararli’s preservatives, including stabilized chlorine dioxide.

Appellants also argue that “the stabilizing effect of citric acid/citrate is unexpected” (App. Br. 4 (emphasis omitted)). In particular, Appellants argue:

Figures 1 and 2[] show the effect of citrate on the stability of both bimatoprost and stabilized chlorine dioxide (Purite[®]). The compositions described on p. 10, Example 3 and Table 4, were identical except for the presence of citric acid. The figures clearly indicate that both drug and preservative suffer about half

as much decomposition when citrate is present. This is clearly unexpected, particularly since Ripley teaches that citric acid activates stabilized chlorine dioxide.

(*Id.* at 5.)

We are not persuaded. The Specification discloses that, “if stabilized chlorine dioxide is in a composition with certain therapeutically active agents, either the stabilized chlorine dioxide, or the therapeutically active agent, or both, are unstable,” but that “[s]urprisingly, citric acid and/or conjugate bases thereof have been discovered to improve the stability of these combinations” (FF 5). In addition, the Specification includes an example showing the recovery after storage of bimatoprost, a therapeutically active agent, and Purite[®], a stabilized chlorine dioxide, from a composition containing citric acid as compared to a composition not containing citric acid (FF 28-31). The evidence shows an increased percent of recovery of both components from the composition containing citric acid (FF 31).

“The evidence presented to rebut a prima facie case of obviousness must be commensurate in scope with the claims to which it pertains.” *In re Dill*, 604 F.2d 1356, 1361 (CCPA 1979). We do not agree that this evidence is commensurate with the scope of claim 16, which does not even recite a therapeutically active agent. In particular, the evidence does not show that citric acid would increase the recovery of stabilized chlorine dioxide in the absence of a therapeutically active agent such as bimatoprost. Thus, we do not agree with Appellants that this evidence is sufficient to overcome the prima facie case that claim 16 would have been obvious.

We conclude that the Examiner has set forth a prima facie case that claim 16 would have been obvious in view of Kararli and Ripley, which

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Appellants have not rebutted. We therefore affirm the rejection of claim 16 under 35 U.S.C. § 103(a). Claims 1-15 and 17-20 fall with claim 16.

CONCLUSION

We affirm the rejection of claims 1-20 under 35 U.S.C. § 103(a). However, we reverse the rejections under 35 U.S.C. § 112, first and second paragraphs.

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

AFFIRMED

cdc

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