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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte WILLIAM J. DUPPS and IBRAHIM SEVEN¹

Appeal 2017-011800
Application 14/165,796
Technology Center 1600

Before RICHARD M. LEOVITZ, JOHN E. SCHNEIDER, and
RACHEL H. TOWNSEND, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal² under 35 U.S.C. § 134 of the Examiner's final rejection of claims to a method for treating astigmatism which have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART.

¹ Appellants identify the Real Party in Interest as The Cleveland Clinic Foundation. Appeal Br. 3.

² We have considered and herein refer to the Specification of Jan. 28, 2014 ("Spec."); Final Office Action of Oct. 13, 2016 ("Final Act."); Appeal Brief of Apr. 13, 2017 ("Appeal Br."); Examiner's Answer of July 31, 2017 ("Ans."); and Reply Brief of Sept. 27, 2017 ("Reply Br.").

STATEMENT OF THE CASE

“Astigmatism is an optical defect in which vision is blurred due to the inability of the optics of the eye to focus a point object into a sharp focused image on the retina.” Spec. ¶ 3. The Specification describes a method for treating astigmatism. Spec. ¶ 4.

Claims 1–3, 8, 10, 11, 13, 14, 16, and 20 are on appeal.³ Claim 1 is representative and reads as follows:

1. A method for treating astigmatism in an eye of a patient comprising:
 - determining an axis of greater curvature of the eye; and
 - applying a stiffening process to a cornea of the eye in a pattern defined from the axis of greater curvature of the eye.

The claims stand rejected as follows:

Claims 1–3, 8, 10, 11, 13, 14, 16, and 20 have been rejected under 35 U.S.C. § 103(a) as unpatentable over El Hage⁴ in view of Bozkurt.⁵

Claims 1–3, 8, 10, 11, 13, 14, 16, and 20 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Karageozian⁶ in view of Bozkurt.

³ Claims 4–7, 9, 12, 15, and 17–19 are pending in the application but have been withdrawn from consideration. Final Act. 1.

⁴ El Hage, US 2009/0171305 A1, published July 2, 2009 (“El Hage”).

⁵ Bozkurt et al., *Topographical analysis of corneal astigmatism in patients with tilted-disc syndrome*, 21 *Cornea* 458 (2002) (abstract only) (“Bozkurt”).

⁶ Karageozian et al., US 6,537,545 B1, issued Mar. 25, 2003 (“Karageozian”).

DISCUSSION

El Hage Combined with Bozkurt

Issue

The issue with respect to this rejection is whether a preponderance of the evidence supports the Examiner's conclusion that the subject matter of the claims would have been obvious over El Hage combined with Bozkurt.

The Examiner finds

El Hage teaches a method of treating astigmatism by correcting the corneal shape by providing a corrective lens for controlled kerato-reformation (CKR) by corneal topograph data from the patient's cornea (reverse geometry of the cornea), monitoring the reformation, and applying a crosslinking agent to the reformed cornea in the amount and manner needed.

Final Act. 4. The Examiner also finds that "El Hage does not expressly teach the shape of the astigmatism such as the bow tie form, but does teach treating the astigmatism by reshaping the cornea after topographical analysis of the cornea and applying a crosslinking agent to the reformed cornea in the amount and manner needed." *Id.* The Examiner goes on to find "Bozkurt et al. teaches that topographic analysis showed that the corneal astigmatism presented with bow tie pattern (i.e. symmetrical, or asymmetric) and had various axis including oblique astigmatism (skewed axis) in patients." *Id.*

The Examiner concludes

it would have been obvious before the effective filing date of the claimed invention to apply the stiffening process to the areas of corneal astigmatism error such as the bow tie and reshape the cornea to correct the refractive error, as suggested by Bozkurt et al., and produce the claimed invention. It is *prima facie* obvious to address a known shape causing the astigmatism being treated like the bowtie form as El Hage expressly teaches

treating astigmatism by correcting the corneal shape with a reverse geometry lens which would be the presented form like a bowtie shape as addressed by Bozkurt and then crosslinked to help maintain the reformed cornea allowing the period of CKR lens wear from once a day to about once a week or once a month or longer; with a reasonable expectation of success absent evidence of criticality for a particular stiffening process or process step.

Id. at 4–5.

Appellants argue that the references do not teach or suggest applying a stiffening process to the cornea in a pattern defined by the axis of greater curvature of the eye. Appeal Br. 6. Appellants contend that neither El Hage nor Bozkurt teach applying the crosslinking treatment in a pattern defined by the axis of greater curvature. *Id.* at 7. Appellants argue that selectively applying the crosslinking agent would render the process of El Hage unsuitable for its intended process. *Id.* Appellants contend that the references do not address or teach the different patterns which can be used in practice of the invention. *Id.* at 8. Appellants also argue that El Hage is limited to use of a corrective lens to reshape the cornea and that the Examiner has not shown how the lens would act to stiffen the cornea. *Id.* at 9.

Findings of Fact

We adopt the Examiner's findings, including with regard to the scope and content of, and motivation to modify or combine, the prior art. Final Act. 3–4. The following findings are included for emphasis and reference purposes.

FF1. El Hage discloses a non-surgical method for reshaping and altering the shape of the cornea. El Hage ¶ 7.

FF2. El Hage teaches that the disclosed method can be used to treat astigmatism. *Id.* ¶ 14.

FF3. El Hage teaches

In one embodiment, the cross-linking agent is applied in an amount sufficient to saturate the cornea and/or be present in the anterior chamber of the eye. When the cross-linking agent is Riboflavin/UV, the riboflavin is applied in an amount and manner that provides a yellow coloration in the anterior chamber of the cornea when viewed, for example, via a slit-lamp. Preferably, the corneal tissue and the anterior chamber show a similar or the same yellow coloration due to riboflavin. In another embodiment, the cross-linking agent is applied in an amount and manner sufficient to increase the rigidity of the cornea (R). The crosslinking agent preferably penetrates at least 3/4 of the corneal tissue, for example, at least 300 mm.

Id. ¶ 11.

FF4. El Hage teaches

The present invention is directed to methods for maintaining a desired shape of the cornea following the wear of corrective CKR™ contact lens(es), for example, reverse geometry contact lens(es) for an extended period of time post-wear. Typically, once the patient's cornea has achieved a desired reshaping and visual acuity, the patient may wear the corrective contact lens for a period of time, for example, 3-8 hours, typically overnight, and retain visual improvement and reshaped cornea for about 12-48 hours. As discussed in the examples below, administering to the CKR™-reformed cornea an effective collagen cross-linking amount of a crosslinking agent such as a photosensitizer (e.g., riboflavin) solution in combination with UV light effectively extends the amount of

time the reformed cornea maintains a desired corneal shape and improved vision.

Id. ¶ 51.

FF5. El Hage also teaches

To effect treatment of astigmatism where the patient's corneal dome has more than one curvature, each at a given axis, the reverse-geometry lens's curvature places the pressure zone to apply pressure at the steepest meridian to effect its reduction and to minimize or eliminate differences in the curvatures. The characteristics of the reverse-geometry lens for treating astigmatism are similar to those for a mold for correcting myopia.

Id. ¶ 58.

FF6. Bozkurt reports the corneal topography of patients with corneal astigmatism. Bozkurt Abstract.

FF7. Bozkurt reports that "Corneal astigmatism was symmetric bow tie pattern in 10 eyes (45.45%), asymmetric bow tie pattern in 11 eyes (50%) and irregular in 1 eye (4.5%)." *Id.*

FF8. Bozkurt also reports that among patients with a bow-tie pattern "14 eyes had with-the-rule astigmatism, 1 eye had against-the-rule astigmatism, and 6 eyes had oblique astigmatism." *Id.*

Principles of Law

[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.

After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the

record, by a preponderance of evidence with due consideration to persuasiveness of argument.

In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

Analysis

With the exception of claim 20 discussed below, we find the Examiner has established that the subject matter of the claims would have been obvious to one of ordinary skill in the art at the time the invention was made over El Hage combined with Bozkurt. Appellants have not produced evidence showing, or persuasively argued, that the Examiner's determinations on obviousness are incorrect. Only those arguments made by Appellants in the Briefs have been considered in this Decision. Arguments not presented in the Briefs are waived. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2015). We have identified claim 1 as representative. Claims 8, 13, and 20 have been argued separately. The remaining claims fall with claim 1. We address Appellants' arguments below.

Appellants contend that the references do not teach or suggest patterned crosslinking to adjust the shape of the cornea without the use of corrective lens. Appeal Br. 6. Appellants also contend that the references do not teach applying the crosslinking treatment in a pattern defined by the axis of greater curvature of the cornea. Appeal Br. 7.

We have considered Appellants' arguments and find them unpersuasive. While El Hage teaches the use of a corrective lens to adjust the shape of the cornea, El Hage also teaches application of a crosslinker to maintain the adjusted shape when the lens is removed. FF4. The crosslinker

helps the cornea maintain its shape by increasing the rigidity of the cornea. FF3. Thus, El Hage teaches a stiffening process.

With respect to determining the axis of greater curvature and defining a pattern based on that axis, El Hage teaches that the shape induced by the reshaping process is determined based on the curvature of the cornea, FF5, and Bozkurt teaches that astigmatism occurs in bowtie shaped patterns. FF7. While neither reference specifically uses the term axis of greater curvature, we find that one skilled in the art would have understood the references to refer to an axis of curvature and to patterns based on that axis.

Appellants contend that the modification of El Hage proposed by the Examiner would render the El Hage system unsuitable for its intended purpose. Appeal Br. 7. Appellants, however, have offered no evidence to support this contention. Attorney argument does not take the place of evidence. *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1581 (Fed. Cir. 1989).

Appellants argue that the combination of references does not teach or suggest the “application of corneal hardening in a pattern matching the presentation of the disease, nor would such application be effective.” Appeal Br. 7–8. We find this argument unpersuasive.

First, as the Examiner points out, claim 1, as drafted, is relatively broad and is not limited to the use of applying a crosslinking agent in a specific pattern. Ans. 8. All that is required is that the stiffening process is applied “in a pattern defined from the axis of greater curvature of the eye.” El Hage specifically teaches the shaping of the cornea using a pattern based in the presentation of the disease. FF5. Bozkurt teaches patterns associated with astigmatism including the species of patterns elected by Appellants.

FF7 & 8; Final Act. 2–3. El Hage teaches application of the crosslinking agent after a contact lens has imposed a pattern on the cornea. FF4. Thus, the stiffening process is necessarily applied in that pattern. Consequently, we agree with the Examiner that the stiffening process of El Hage meets the requirements of claim 1 calling for the application of the stiffening process in a pattern.

Appellants contend that El Hage requires the use of a corrective lens to induce the shape on the cornea and the present claims do not call for the use of a corrective lens. Appeal Br. 9. Appellants also argue that the use of the lens in El Hage does not, by itself, induce stiffening of the cornea. *Id.*

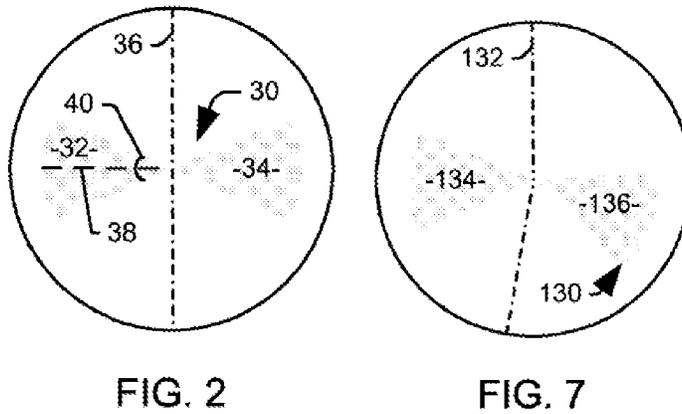
Appellants' arguments are unpersuasive. The present claims use the term "comprising" which allows for the use of additional steps which can include the application of a corrective lens. Ans. 9.

Claim 8

Claim 8 depends from claim 1, and further recites "wherein the pattern is defined such that substantially none of the axis of greater curvature of the cornea is included in the application of the stiffening process."

Appellants contend that claim 8 calls for the stiffening pattern to be defined such that substantially none of the axis of greater curvature is included in the stiffening process. Appeal Br. 9. Appellants contend that the references do not teach or suggest such a pattern. *Id.* We find this argument unpersuasive.

Appellants elected the patterns shown in Figures 2 and 7 (shown below) of the application for examination. Final Act. 2–3.



Figures 2 and 7 of El Hage showing patterns for treating astigmatism.

In the figures lines 36 and 132 represent the axes of greater curvature. Spec. ¶¶ 23 and 31. Shaded areas 32, 34, 134, and 136 represent the pattern for stiffening. *Id.* As shown in the figures the bowtie patterns do not include a significant portion of the axes of greater curvature. Bozkurt teaches symmetric and asymmetric bowtie patterns associate with astigmatism. FF7. One skilled in the art would understand that these bowtie patterns would lie about an axis of curvature as suggested by El Hage. FF5. The patterns taught by Bozkurt do not include a substantial portion of the axis of curvature. El Hage directs one of ordinary skill in the art to apply the cross-linking agent to maintain the desired corneal shape. FF4. Because the pattern is substantially outside the axis of curvature, as the Examiner found, one of ordinary skill in the art would not have had reason to stiffen it along such axis. Thus, the references do teach or suggest the pattern embraced by claim 8.

Claim 13

Claim 13 depends from claim 1 and further recites: “wherein applying a stiffening process to a cornea of the eye comprises applying the stiffening process such that one of a stiffening agent dosage, a penetration depth, an exposure time, and a spatial energy profile of an associated light source of the stiffening process is a function of at least one other optical parameter.”

Appellants contend that neither El Hage nor Bozkurt teach or suggest the claimed limitation. Appeal Br. 10–11.

We find Appellants’ argument unpersuasive. As taught by the Specification, another optical parameter is a parameter other than the axis of greater curvature which can include the magnitude of the astigmatism. Spec. ¶¶ 5, and 16. El Hage teaches correcting astigmatism by minimizing or eliminating the difference in more than one curvature of the cornea, and thus the additional curvature would serve as at least one other parameter. FF5. We find that one skilled in the art would understand that one would need to know the magnitude of the astigmatism in order to determine if the stiffening process produced the desired change in curvature.

El Hage also teaches adjusting the amount of crosslinking agent and UV light exposure to achieve the desired results. *See, e.g.*, El Hage ¶¶ 64, 65, and 68. Thus, El Hage teaches the additional elements of claim 13.

Claim 20

With respect to independent claim 20, Appellants contend that the references do not teach or suggest the second recited stiffening process

which is applied in a homogeneous pattern across the entire cornea. Appeal Br. 12. We agree with Appellants that the references do not teach a second stiffening step.

The Examiner contends that the application of the corrective lens in El Hage constitutes the first stiffening step and the application of the chemical agents constitutes the second stiffening step. Ans. 9. We do not agree with the Examiner's interpretation of El Hage. While El Hage teaches that the application of the corrective lens induced shape changes in the cornea, El Hage also teaches that the changes induced by the corrective lens are short lived absent application of the crosslinker. *See* El Hage ¶ 5 (need to wear lens each day for three to eight hours with improved vision maintained when not wearing the lenses.) El Hage is directed to a method for improving the duration of the shape changes induced by the corrective lenses. El Hage ¶ 7. We agree with Appellants that the application of the corrective lens does not constitute a first stiffening step as recited in claim 20.

Conclusion of Law

We conclude that a preponderance of the evidence supports the Examiner's conclusion that the subject matter of claims 1, 8, and 13 would have been obvious over El Hage combined with Bozkurt.

We conclude that a preponderance of the evidence does not support the Examiner's conclusion that the subject matter of claim 20 would have been obvious over El Hage combined with Bozkurt.

Claims 2, 3, 10, 11, 14, and 16, have not been argued separately and therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

Karageozian Combined with Bozkurt

Issue

The issue with respect to this rejection is whether a preponderance of the evidence supports the Examiner's conclusion that the subject matter of the claims would have been obvious over Karageozian combined with Bozkurt.

The Examiner finds that Karageozian teaches "a method of treating astigmatism by providing a corneal hardening agent (i.e. crosslinker) either before placement or within a rigid corrective lens with the desired configuration, monitoring the reformation, and then removing the lens after the reformation is complete." Final Act. 7. The Examiner finds that Karageozian teaches that the method can be used to treat astigmatism. *Id.* The Examiner goes on to find that while Karageozian does not teach the elected bowtie pattern, Karageozian teaches that the "lens configuration can be any pattern necessary to accommodate the needs [of the] patient." Final Act. 8. The Examiner finds that Bozkurt's "topographic analysis showed that the corneal astigmatism presented with bow tie pattern (i.e. symmetrical, or asymmetric) and had various axis including oblique astigmatism (skewed axis) in patients." *Id.*

The Examiner concludes

it would have been obvious before the effective filing date of the claimed invention to apply the corneal hardening and/or lens process which can also have the corneal hardener within the lens; to the areas of corneal astigmatism error such as the bow tie and reshape the cornea to correct the refractive error, as suggested by Bozkurt et al., and produce the claimed invention. It is *prima facie* obvious to address the shape causing the astigmatism being treated like the bowtie form as Karageozian expressly teaches treating astigmatism by correcting the corneal

shape with a corneal hardener and a corrective (e.g. reverse geometry) lens that can be in whatever any pattern necessary to accommodate the needs of a patient which would be the presented form like a bowtie shape as addressed by Bozkurt; with a reasonable expectation of success absent evidence of criticality for a particular stiffening process or process step.

Id.

Appellants contend that the references do not teach or suggest applying a stiffening process to the cornea in a pattern defined by the axis of greater curvature. Appeal Br. 13. Appellants contend that the same arguments presented with respect to the combination of El Hage and Bozkurt are applicable to the combination of Karageozian and Bozkurt.

Findings of Fact

FF9. Karageozian discloses a method for “accelerating non-surgical corneal reshaping involving the release of corneal hardening agents which facilitate reshaping of the cornea to correct refractive errors of the eye.” Karageozian col. 1, ll. 20–22.

FF10. Karageozian teaches that the disclosed method can be used to treat astigmatism. Karageozian col. 17, ll. 47–48.

FF11. The method of Karageozian includes the steps of

selecting a pharmaceutically acceptable corneal hardening agent on the basis of its being able to harden the cornea in said eye of said subject mammal without causing damage to said cornea;

administering to said eye of said subject mammal a corneal hardening amount of said agent so that said cornea can be reshaped from a first configuration to a desired second configuration;

fitting said cornea with a rigid contact lens having a concave curvature of said desired second configuration; permitting said cornea to reshape to said desired second configuration under the influence of said lens; and removing said lens when said cornea is capable of maintaining said desired second configuration without the support of said lens; wherein said corneal hardening agent is glycerinaldehyde.

Karageozian col. 47, l. 27 – col. 48, l. 11 (claim 1).

FF11. Karageozian teaches

Astigmatism is a refractive error of the lens system, caused usually by an oblong shape of the cornea. In this condition, the central corneal curvature is uneven, resulting in a stretching of the image on the retina. The horizontal and vertical central meridians are of different curvatures. The astigmatism contact lenses may use toric and aspheric base curves, intermediate curves, and peripheral curves that may incorporate prism and/or truncation. The initially flatter central meridian of the eye is reshaped to take on a steeper curvature and the initial steeper curvature and the initial steeper central meridian is reshaped to take on a flatter curvature. This process reshapes the central corneal curvature to a spherical shape and eliminates astigmatism.

Karageozian col. 25, ll. 10–22.

FF12. Karageozian teaches an examination of the cornea including the clarity of the cornea; pachymetry to measure the thickness of the cornea; computer-assisted corneal topography to evaluate surface topographical changes; measurement of the tensile strength of the cornea; measurement of the distensibility of the cornea; keratometry to measure central corneal curvature; and retinoscopy to measure the refractive error of

the cornea can be used to determine the nature and amount of the hardening agent used. *See* Karageozian col. 11, ll. 24–46.

Analysis

With the exception of claim 20 discussed below, we find the Examiner has established that the subject matter of the claims would have been obvious to one of ordinary skill in the art at the time the invention was made over Karageozian combined with Bozkurt. Appellants have not produced evidence showing, or persuasively argued, that the Examiner's determinations on obviousness are incorrect. Only those arguments made by Appellants in the Briefs have been considered in this Decision. Arguments not presented in the Briefs are waived. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2015). We have identified claim 1 as representative. Claims 8, 13, and 20 have been argued separately. The remaining claims fall with claim 1. We address Appellants' arguments below.

Appellants contend that the references do not teach or suggest applying a stiffening process to the cornea in a pattern defined by the axis of greater curvature. Appeal Br. 13–14. We are not persuaded by Appellants' argument.

As discussed above, we do not read claim 1 as requiring that the hardening agent be applied in a pattern only that the stiffening process be in a pattern. Like El Hage, Karageozian discloses a method for treating astigmatism by reshaping the cornea in a specific pattern using a hardening agent to maintain the pattern for a period of time. FF9–11. As in El Hage, Karageozian teaches the application of the contact lens to impose a pattern on

the cornea which is then locked-in using the hardening agent. Bozkurt discloses that astigmatism occurs in specific patterns including the bowtie pattern elected by Appellants. FF7. We agree with the Examiner that it would have been obvious to one skilled in the art to use the bowtie pattern of Bozkurt in the method of Karageozian to treat astigmatism. In so doing, because the stiffening process is applied when the pattern is imposed on the cornea, the stiffening process of Karageozian meets the requirements of claim 1 calling for the application of the stiffening process in a pattern.

Appellants remaining arguments mirror those made with respect to El Hage discussed above. For the reasons stated above, we find these arguments unpersuasive.

Claim 8

Appellants argue that the references do not teach using a pattern that does not include a substantial portion of the axis of greater curvature.

Appeal Br. 15–16. We are not persuaded.

As discussed above, the bowtie patterns disclosed by Bozkurt do not include a substantial portion of the axis of greater curvature and there would be no reason to harden outside these regions. According, the Examiner's determination that combination Karageozian and Bozkurt renders the subject matter of claim 8 obvious is supported by a preponderance of the evidence.

Claim 13

As with the rejection based on El Hage combined with Bozkurt, Appellants contend that the combination of Karageozian and Bozkurt does not teach “applying the stiffening process such that one of a stiffening agent dosage, a penetration depth, an exposure time, and a spatial energy profile of an associated light source of the stiffening process [as] a function of at least one other optical parameter.” Appeal Br. 16.

We have considered Appellants’ argument and find it unpersuasive. Karageozian teaches that the nature and amount of hardening agent can be assessed using optical parameters such as the thickness and topography of the cornea. FF12. Thus, Karageozian uses such information to determine the efficacy of the hardening agent and its dosage to apply to the human cornea.

Claim 20

With respect to claim 20, Appellants contend that the references do not teach or suggest a second stiffening process applied in a homogeneous pattern across the entire cornea. Appeal Br. 17–18. We agree with Appellants that the references do not teach a second stiffening step.

The Examiner contends that the application of the corrective lens in Karageozian constitutes the first stiffening step and the application of the chemical agents constitutes the second stiffening step. Ans. 11. We do not agree with the Examiner’s interpretation of Karageozian. While Karageozian teaches that the application of the corrective lens induced shape changes in the cornea, Karageozian also teaches that the changes induced by

the lens are short lived absent application of the crosslinker. *See* Karageozian col. 2, l. 60–67 (contact lenses must be worn to stabilize the changes.) Like El Hage, Karageozian is directed to a method for improving the duration of the shape changes induced by the corrective lenses. Karageozian col. 3, ll. 23–35. We agree with Appellants that the application of the corrective lens does not constitute a first stiffening step as recited in claim 20.

Conclusion of Law

We conclude that a preponderance of the evidence supports the Examiner’s conclusion that the subject matter of claims 1, 8, and 13 would have been obvious over Karageozian combined with Bozkurt.

We conclude that a preponderance of the evidence does not support the Examiner’s conclusion that the subject matter of claim 20 would have been obvious over Karageozian combined with Bozkurt.

Claims 2, 3, 10, 11, 14, and 16, have not been argued separately and therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

SUMMARY

We affirm the rejections of claims 1–3, 8, 10, 11, 13, 14, and 16 under 35 U.S.C. § 103(a).

We reverse the rejections of claim 20 under 35 U.S.C. § 103(a).

Appeal 2017-011800
Application 14/165,796

TIME PERIOD FOR RESPONSE

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-IN-PART