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EXAMINER

FAIRCHILD, MALLIKA DIPAYAN

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte FRANK RISI, COLIN IRWIN,
JAY T. RUBINSTEIN, FELIPE SANTOS, and
JAMES O. PHILIPS

Appeal 2017-010453
Application 14/744,951
Technology Center 3700

Before JEFFREY N. FREDMAN, DEBORAH KATZ, and JOHN G. NEW,
Administrative Patent Judges.

FREDMAN, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal^{1,2} under 35 U.S.C. § 134 involving claims to a vestibular stimulation device. The Examiner rejected the claims as indefinite and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

¹ Appellants identify the Real Parties in Interest as Cochlear Limited and University of Washington Center for Commercialization (*see* App. Br. 3).

² We have considered and herein refer to the Specification of Oct. 1, 2015 (“Spec.”); Final Office Action of Aug. 30, 2016 (“Final Act.”); Appeal Brief of Apr. 5, 2017 (“App. Br.”); Examiner’s Answer of June 2, 2017 (“Ans.”); and Reply Brief of Aug. 2, 2017 (“Reply Br.”).

Statement of the Case

Background

The vestibular system “is a portion of the inner ear which enables the sensation of angular and linear motion” and “includes the three semicircular canals” (Spec 1:7–12). Abnormalities of the vestibular system, such as Ménière’s disease, “can result in significant disability” (Spec. 1:12–17). The prior art proposes to treat vestibular disease by “provid[ing] a vestibular stimulator using electrical stimulation” (Spec. 1:29–33). A known vestibular stimulation device uses “electrodes placed externally, or implanted neural stimulation electrodes” (*id.*). The Specification teaches “an electrode array suitable for implantation within one or more semicircular canals of a user, so as to facilitate vestibular stimulation” (Spec. 2:1–3).

The Claims

Claims 20–42 are on appeal. Independent claim 20 is representative and reads as follows:

20. A vestibular system stimulation array, comprising:

at least one electrode array configured to be implanted in a semicircular canal of the vestibular system, and further configured to apply electrical stimulation to the vestibular system while implanted in the semicircular canal, wherein the at least one electrode array is dimensioned such that residual vestibular function of the semicircular canal in which the at least one electrode array is implanted is retained, and wherein the electrode array comprises a stiffener embedded in the electrode array.

*The Issues*³

- A. The Examiner rejected claims 22, 25, 26, 28, 34, 35, 38, 41, and 42 under 35 U.S.C. § 112(pre-AIA), second paragraph, as indefinite (Final Act. 8–10).
- B. The Examiner rejected claims 20–39, 41, and 42 under 35 U.S.C. § 103(a) as obvious over Della Santina,⁴ Gantz,⁵ and Zhulati⁶ or Thenuwara⁷ (Final Act. 10–19).
- C. The Examiner rejected claim 40 under 35 U.S.C. § 103(a) as obvious over Della Santina, Gantz, and Zhulati or Thenuwara, further in view of Kuzma⁸ (Final Act. 19–20).

A. *35 U.S.C. § 112(pre-AIA), second paragraph*

The Examiner finds several claim terms are not defined in the originally filed Specifications and thus indefinite (Final Act. 8–9). We will address these findings together.

The Examiner finds claims 22, 28, and 35 are indefinite because “the term ‘substantially’ makes the limitation[s] ‘does not substantially compress

³ Because the Examiner, in the Advisory Action mailed Mar. 6, 2017, entered Appellants’ After-Final amendment filed Feb. 24, 2017 that amended claim 37 to address the 35 U.S.C. § 112(pre-AIA), second paragraph rejection, and the Examiner does not restate this rejection in the Answer, we treat this rejection as withdrawn by the Examiner.

⁴ Della Santina et al., US 7,225,028 B2, issued on May 29, 2007.

⁵ Gantz, US 2008/0312717 A1, published on Dec. 18, 2008.

⁶ Zhulati et al., US 8,532,788 B2, issued on Sept. 10, 2013.

⁷ The Examiner applied Thenuwara et al., US 2011/0295352, published on Dec. 1, 2011, as an alternative to Zhulati. Since the references are cited in the alternative, we choose to address only Zhulati in our decision.

⁸ Kuzma, US 5,545,219, issued on Aug. 13, 1996.

the membranous labyrinth’ and ‘the membranous labyrinth remains substantially uncompressed’ unclear” (Final Act. 8–9).

The Examiner also finds claims 25, 26, 34, 38, 39, and 41 indefinite because the term “about,” makes the dimensions of the claimed electrode array unclear (Final Act. 9).

The Examiner also finds claims 41 and 42 indefinite because the term “substantially,” makes “substantially an entire length,” unclear (*id.*).

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s position that claims 22, 25, 26, 28, 34, 35, 38, 41, and 42 are indefinite?

Findings of Fact

1. The Specification teaches:

It is desirable that the array have sufficient stiffness and dynamics such that the electrode can be placed reliably within the labyrinth. The electrode array according to this implementation incorporates a stiffening member with unique characteristics, allowing the electrode array to be of the required diameter, yet of sufficient stiffness to insert to the desired depth between the bony labyrinth and the membranous labyrinth of each semicircular canal. The array should have a stiffness allowing a signal stroke atraumatic insertion to the required depth in the canal. On the other hand, it must also have sufficient flexibility to deflect and avoid damage to the delicate anatomical structures. If the array is too stiff, it would be more prone to pierce or compress the delicate anatomical structures: if it is too soft or flexible, the electrode array may buckle and deform during insertion, and thereby cause trauma.

(Spec. 10:26–11:4).

2. Figure 4 of the Specification is reproduced, in part, below:

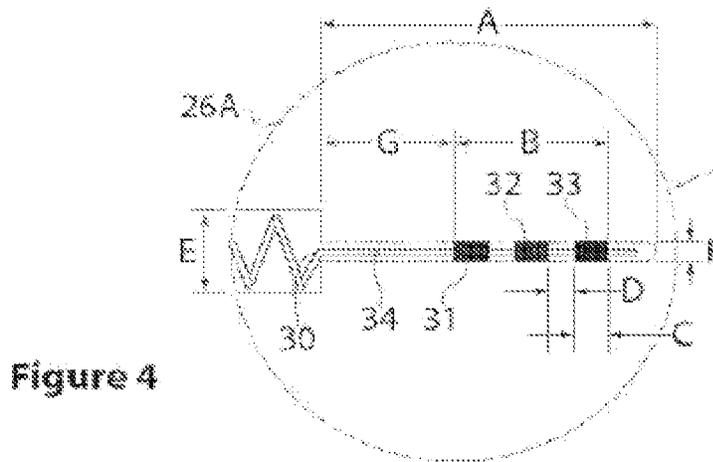


Figure 4

Figure 4 illustrates a detailed view of the electrode array with several dimensions, including length of the array A, electrode span B, diameter of insertion part F, and embedded stiffener 34 (Spec. 11:3–13).

Principles of Law

“[C]laims are required to be cast in clear—as opposed to ambiguous, vague, indefinite—terms.” *In re Packard*, 751 F.3d 1307, 1313 (Fed. Cir. 2014). “[T]his requirement is not a demand for unreasonable precision. The requirement, applied to the real world of modern technology, does not contemplate in every case a verbal precision of the kind found in mathematics.” *Id.*

Analysis

We now address the Examiner’s indefinite issues.

“does not substantially compress,” “substantially uncompressed”

Appellants contend that the Specification describes an electrode array, having a diameter and stiffness, that does not compress (and thus damage) the membranous labyrinth (App. Br. 18–19). Appellants contend that “[a] person of ordinary skill in the art would readily understand, based upon the

device at hand, what level of compression would cause such damage” (App. Br. 18).

We agree with Appellants that claims 22, 28, and 35 are not indefinite because the relative terms “does not substantially compress” and “substantially uncompressed” do not render the claim scope unclear to one skilled in the art. As seen above, the Specification describes compression in the context of avoiding trauma to the vestibular system’s delicate anatomical structures (FF1). A person of skill in the art would understand that the claim terms are reasonably interpreted to allow some degree of compression so long as trauma to the membranous labyrinth is avoided. Relative terms such as “substantially” do not render patent claims so unclear as to prevent a person of skill in the art from ascertaining the scope of the claim. *Deere & Co. v. Bush Hog*, 703 F.3d 1349, 1359 (Fed. Cir. 2012).

“*about*”

Appellants contend “the lengths of ‘about 1.15 mm,’ and ‘about 150 microns’” are “definite because infringement could clearly be assessed by a person of ordinary skill in the art through use of, for example, calipers” (App. Br. 20, *citing* MPEP § 2173.05(b)). Appellants further exemplify use of “about” in the prior art cited by the Examiner (App. Br. 20–21, *citing* MPEP § 2173.02(II)).

We agree with Appellants because the Specification provides dimensions (1.15 mm and 150 microns) such that the electrode is placed reliably in the labyrinth without causing trauma (FF1, FF2). The term “about” can be understood in light of the technology embodied by the invention, as shown by the Specification and the prior art, to encompass the claimed dimensions within a reasonable degree of precision so as to avoid

trauma. *See Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1557 (Fed. Cir. 1996).

“substantially an entire length”

Appellants contend “[a] person of ordinary skill in the art would readily understand, based upon the Specification . . . what portion of the electrode . . . would constitute ‘substantially an entire length’ to provide” atraumatic insertion and avoid damage to delicate anatomical structures (App. Br. 18–19). Appellants further exemplify use of the terms “substantially” to modify dimensions in the prior art cited by the Examiner (App. Br. 19, *citing* MPEP § 2173.02(II)).

We agree with Appellants because the claim term “substantially an entire length” is reasonably interpreted as requiring that the arrays comprise a stiffness along an entire length or along a length slightly less than the entire length, as seen in Figure 4 (FF2) where the embedded stiffener 34 extends almost entirely along length A. While this is broad, it is not indefinite because “breadth is not to be equated with indefiniteness.” *In re Miller*, 441 F.2d 689, 693 (CCPA 1971).

Conclusions of Law

The evidence of record does not support the Examiner’s position that the claim terms “does not substantially compress,” “substantially uncompressed,” “about” and “substantially an entire length” are indefinite.

B. 35 U.S.C. § 103(a) over Della Santina, Gantz, and Zhulati

The Examiner finds Della Santina teaches “a trifurcated electrode array . . . as shown in 200 Fig 2A, D and also teaches this electrode assembly is inserted into the vestibular labyrinth” (Ans. 7). The Examiner

acknowledges Della Santina “does not teach the claimed dimensions . . . and thus does not teach that the electrode array is dimensioned such that residual vestibular function of the semicircular canal in which the at least one electrode array is implanted is retained” (*id.*).

The Examiner finds Gantz “teaches a lead with an electrode array with a diameter of 0.1–0.4 mm . . . and also teaches an insertable portion of the electrode array (i.e. span) of the electrode array is 8–15 mm” (Ans. 7–8). The Examiner finds Zhulati teaches a stiffener in an electrode array (Ans. 8–9).

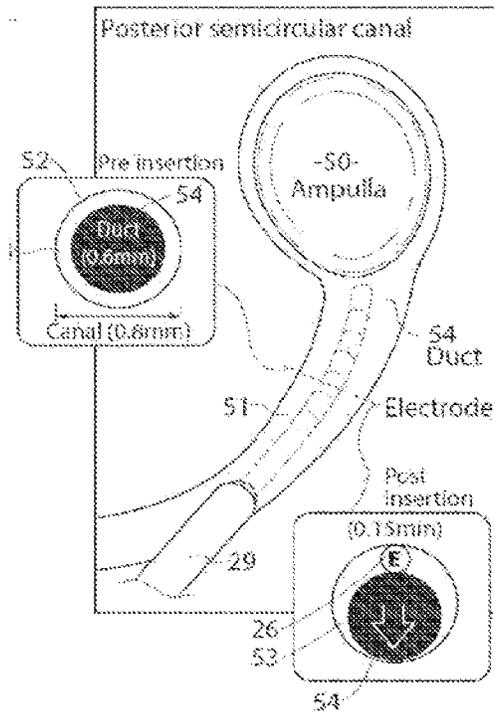
The Examiner finds it obvious to “modify the teachings of Della Santina with a lead having an electrode array diameter of 0.1–0.4 mm and a span as taught by Gantz in order to provide the predictable results of having an easily insertable electrode array” (Final Act. 11). The Examiner finds it obvious to “modify the teachings of Della Santina in view of Gantz with the stiffening member as taught by [] Zhulati in order to provide the predictable results of ensuring that the electrode array can be easily manipulated during insertion” (Final Act. 12).

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s conclusion that Della Santina, Gantz, and Zhulati render claims 20–39, 41, and 42 obvious?

Findings of Fact

3. The Specification teaches “[t]he array 26 is inserted within the canal, proximate to the ampulla 50, between the bony labyrinth 52 and the membranous labyrinth 53” (Spec. 10:2–3).

4. Figure 7 of the Specification is reproduced below:



“Figure 7 [] illustrates the appropriate fit of the electrode array [T]he electrode array 26 lies next to, but not compressing or penetrating the membranous labyrinth 53, with duct 54 intact. The diameter of the array is selected to be sufficiently small to achieve this” (Spec. 10:6–10).

5. The Specification teaches: “the insertion depth is controlled, so as to prevent the potential damage to the ampulla. . . . In a preferred form, the part of the array for insertion is 2.5 mm long, and a stopper is provided to prevent further insertion” (Spec. 10:11–14).

6. The Specification teaches “[i]t is preferred that the electrode array . . . has a diameter of 150 microns or less” (Spec. 11:15–17).

10. Della Santina teaches the “system advantageously is flexible in its application so as to meet the particular needs and wants of a given patient at a given time, including the ability to adapt to a range of head sizes and shapes” (Della Santina 15:7–10).

11. Gantz teaches a cochlear implant that includes an electrode array with a collar (Gantz ¶ 108). “The collar **35** . . . prevents further penetration of the electrode array **30** into the cochlea” (Gantz ¶ 102).

12. Figure 2A of Gantz is reproduced below:

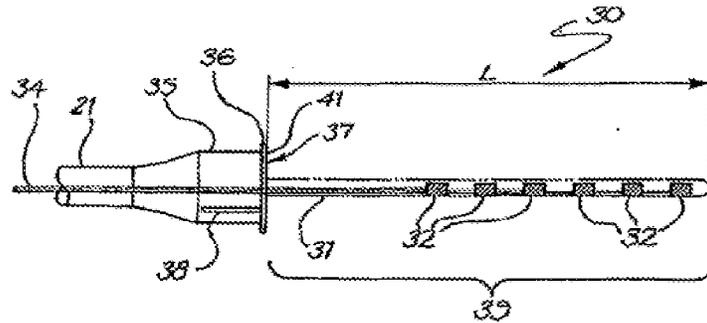


FIG. 2a

Figure 2A shows an electrode array 30, including a length L, electrodes 32, and collar 35 (Gantz ¶ 104). “The length of the inserted portion of the array L is preferably set to be between 8–15 mm” (Gantz ¶ 109).

13. Gantz teaches:

As shown in FIGS. 2a and 2b, the electrode contacts **32** are positioned on the medial side of the electrode array In normal hearing, the oscillation of the basilar membrane is required and the amplitude of the sound is depend[e]nt on the damping of the membrane motion by the fluid within the cochlea. Therefore, it is important that when an electrode array is inserted into the cochlea with the intention to preserve this natural capacity to detect sounds, as is the case with the present invention, the volume of the array must be minimised [sic] so that this damping will not be affected by the exclusion of the

cochlea fluid. The electrode array **30** is of a smaller diameter than a conventional electrode array, and in the embodiment as shown, includes only 6 electrodes **32**.

(Gantz ¶ 106).

14. Gantz teaches “the electrode array is shown as having a substantially constant diameter along its length of between 0.1 and 0.4 mm”

(Gantz ¶ 108).

15. Zhulati teaches a lead 100 with a “stiffener **108** [] shown as a tube **124** . . . made of Nitinol, stainless steel or other bio-compatible materials. Tube **124** preferably possesses as substantially constant diameter along its length” (Zhulati 4:19–29).

16. Zhulati teaches “the stiffener [] may be dimensioned to conform to the anatomy of a patient” and may be “made from a super-elastic Nitinol alloy” where “[t]he exterior diameter of the stiffener may be ‘0.021 and an interior diameter of 0.017’” (Zhulati 7:26–43).

Principles of Law

“The combination of familiar elements according to known methods is likely to be obvious when it does not more than yield predictable results” *KSR Int 'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). “Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456 (CCPA 1955), *see also*, *In re Applied Materials*, 692 F.3d 1289, 1295 (Fed. Cir. 2012) (“the prior art discloses dimensional values overlapping the ranges claimed in [the] Patents).

Analysis

We adopt the Examiner’s findings of fact and reasoning regarding the scope and content of the prior art (Final Act. 10–19; FF 3–16) and agree that

the claims are rendered obvious by Della Santina, Gantz, and Zhulati. We address Appellants' arguments below.

Claims 20, 22, 27, and 28

Appellants contend the functional language “dimensioned,” “configured to,” and “configured for” should be interpreted as structural limitations (App. Br. 23, 27 and 31–32). For example, Appellants contend “preservation of the residual vestibular function is achieved using a suitable dimension, for example for a circular array, a diameter less than 150 microns” (App. Br. 23). Appellants further contend “particular structural features relating to flexibility, stiffness, and diameter are all relevant to an apparatus configured such that the electrode array does not substantially compress [a] membranous labyrinth” (App. Br. 27).

Based on this understanding, Appellants contend none of the references disclose: “an electrode array dimensioned to preserve residual vestibular function” (App. Br. 23); “an electrode array configured to be ‘implanted in the semicircular canal such that the electrode array does not substantially compress a membranous labyrinth of the semicircular canal’” (App. Br. 28); or “configured for operable insertion between a bony labyrinth and a membranous labyrinth of the vestibular system” (App. Br. 31) (internal quotations removed).

We find these arguments unpersuasive because we agree with the Examiner that the prior art combination would “result in retaining residual function since those ranges fall within the applicant’s disclosed diameter range and would necessarily retain function as well” (Final Act. 11). In particular, the Examiner cited Gantz’ teaching that “it is important that when an electrode array is inserted into the cochlea with the intention to preserve

[its] natural capacity to detect sounds . . . the volume of the array must be minimised [sic] so that this damping will not be affected by the exclusion of the cochlea fluid” (FF 13). Thus, Gantz recognizes the need to dimension the electrode array to retain function (FF 13) and Della Santina also teaches the need to optimize to the particular patient (FF 10).

As combined, Della Santina and Gantz (and Zhulati) teach an electrode array (FF 7–10), the array being implantable into the semicircular canals (FF 8) and having a structure, e.g., a minimized diameter of 0.1 mm (FF 14), which is dimensioned to preserve residual vestibular function without compression (FF 13). Similarly, the electrode array with a minimized diameter would have a structure sufficiently small to be implantable between a bony labyrinth and a membranous labyrinth so as not to substantially compress the membranous labyrinth (*see* FF 13).

We therefore find that it is the combination of Della Santina’s vestibular stimulation electrode array system (FF 7–10), Gantz’ electrode array sizes and diameters (FF 12, 14) and teaching to dimension to retain internal cochlea fluid function (FF 13) with Zhulati’s stiffeners (FF 15–16) that renders the claims obvious. We are therefore not persuaded by Appellants’ separate arguments regarding the references because “[n]on-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references.” *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

Claims 21, 29, 32, 35, 41, and 42

Appellants contend:

At least in light of the Specification, a person of ordinary skill in the art would understand that the broadest reasonable interpretation of a stiffness comparable to a 0.12 mm platinum

wire would include only a stiffness that was similar to or had equivalent qualities to the stiffness of a 0.12 mm platinum wire because that stiffness would prevent damage to anatomical structures as described in the Specification. A person of ordinary skill in the art would not consider the broadest reasonable interpretation to include any stiffness just because any stiffness could be *compared to* the stiffness of platinum. Accordingly, none of the cited references disclose this element.

(App. Br. 26).

We agree with the Appellants that “stiffness” should be interpreted as a stiffness that would prevent damage to anatomical structures as described in the Specification. As to the argument that “none of the cited references disclose this element,” we find this unpersuasive because, as noted by the Examiner, Zhulati teaches a stiffener for an electrode dimensioned to conform to the anatomy of a patient (FF 16; *cf.* Ans. 9). Given the desire to conform to the anatomy of the semicircular canals while preserving their natural capacity, it would have been within the level of ordinary skill in the art to discover an optimum value of stiffness. “[D]iscovery of an optimum value of a result effective variable...is ordinarily within the skill of the art.” *Applied Materials*, 692 F.3d at 1295. Appellants do not identify any unexpected results or other secondary consideration, commensurate in scope with the claim, to consider with the Examiner’s prima facie case of obviousness relying on optimization of Zhulati’s teaching of stiffeners “dimensioned to conform to the anatomy of a patient” (FF 16).

Claims 25 and 38

Appellants contend the “span is the length from a beginning of a first electrode to the end of a last electrode,” and that “none of the disclosure

cited in Gantz teaches or suggests a span ‘of about 1.15 mm’” (App. Br. 30–31).

Although we agree with Appellants’ interpretation of “span,” we do not find Appellants’ argument persuasive as to the Examiner’s obviousness rejection. Della Santina teaches a *vestibular* array with 1 to 22 spaced-apart electrodes and a *cochlear* array having 8 to 22 contacts (FF 7 and 9). Gantz teaches a *cochlear* array having a length dimension between 8 mm–15 mm with a span including 6 electrodes (FF 12–13). The Examiner’s conclusion is that it would have been obvious to modify Della Santina’s *vestibular* array, in view of Gantz’s teaching on dimensions of cochlear arrays, to have an electrode span of about 1.15 mm “in order to provide the predictable results of having an easily insertable electrode array” (Final Act. 11). The predictable results of an easily insertable *vestibular* array include the span of the vestibular electrodes being sized so the distance between electrodes fits in “a given patient at a given time” as taught by Della Santina (FF 10).

As we “take account of the inferences and creative steps that a person of ordinary skill in the art would employ,” we find a person of ordinary skill in the art would have reasonably optimized the electrode span of Della Santina, Gantz, and Zhulati in order to be able to fit within the semicircular canal as required. *KSR Int’l*, 550 U.S. at 418; *see also id.* at 421 (“A person of ordinary skill is also a person of ordinary creativity, not an automaton”). Likewise, it is also well settled that a reference stands for all of the specific teachings thereof as well as the inferences one of ordinary skill in the art would have reasonably been expected to draw therefrom. *See In re Fritch*, 972 F.2d 1260, 1264–65 (Fed. Cir. 1992). Here, an ordinarily skilled artisan would reasonably infer that a device intended to be implanted into the

semicircular canal would require an electrode span small enough to fit within the space which would be a matter of routine optimization (*see* FF 10 where Della Santina teaches the “system advantageously is flexible in its application so as to meet the particular needs and wants of a given patient at a given time, including the ability to adapt to a range of head sizes and shapes”).

Claims 23, 24, 26, 30, 31, 33, 34, 36, 37, and 39

Appellants do not separately argue these obviousness rejections, instead relying on their arguments to overcome the combination of Della Santina, Gantz, and Zhulati. Having affirmed the obviousness rejection of claims 20, 29, and 32 from which these claims depend for the reasons given above, we also conclude the claims are obvious for the reasons given by the Examiner.

Conclusion of Law

The evidence of record supports the Examiner’s conclusion that Della Santina, Gantz, and Zhulati render claims 20–39, 41, and 42 obvious.

*C. 35 U.S.C. § 103(a) over Della Santina, Gantz, Zhulati, and Kuzma
Claim 40*

Appellants contend “the wire is not a stiffener but instead ‘a series of insulated electrical conductors 56’ that connect to electrode elements (55)” (App. Br. 33). Appellants further contend “the combination would lack the claimed stiffener and merely have a wire that extends to create a linkage with a positioning member” (App. Br. 34).

We find these arguments unpersuasive because the Appellants attack the references individually rather than address what the references suggest

together. *Merck*, 800 F.2d at 1097. Considering the teachings of the references as a whole, the Examiner relies on Kuzma’s teachings to suggest “modifying the stiffener in view of Gantz and [] Zhulati to extend beyond the distal most electrode as claimed” (Ans. 12). The Examiner finds Kuzma teaches “wires embedded in an electrode array that extends beyond a distal most electrode in an electrode array (e.g. 56a, Fig 12, Col. [11], 43–46) as well as a positioner that extends beyond the distal most electrode . . . (e.g. 52, Fig 12, 23)” (*id.*). We agree with the Examiner that the combination of the art provides a reason to extend the stiffener distal beyond the distal electrode “in order to provide the predictable results of providing the clinician with more control of the lead during implantation” (Final Act. 20).

Conclusion of Law

The evidence of record supports the Examiner’s conclusion that Della Santana, Gantz, Zhulati, and Kuzma render claim 40 obvious.

SUMMARY

In summary, we reverse the rejection of claims 22, 25, 26, 28, 34, 35, 38, 39, 41, and 42 under 35 U.S.C. § 112(pre-AIA), second paragraph.

We affirm the rejection of claims 20–39, 41, and 42 under 35 U.S.C. § 103(a) over Della Santana in view of Gantz and Zhulati.

We affirm the rejection of claim 40 under 35 U.S.C. § 103(a) over Della Santana in view of Gantz and Zhulati, further in view of Kuzma.

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