United States Court of Appeals for the Federal Circuit

COCHLEAR BONE ANCHORED SOLUTIONS AB,
Appellant

v.

OTICON MEDICAL AB, OTICON MEDICAL LLC, WILLIAM DEMANT HOLDING A/S,
Cross-Appellants

2019-1105, 2019-1106

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2017-01018, IPR2017-01019.

Decided: May 15, 2020

LAURA BURSON, Sheppard, Mullin, Richter & Hampton LLP, Los Angeles, CA, argued for appellant. Also represented by BRUCE G. CHAPMAN; MARK PATRICK, Washington, DC.

DAVID R. ANDERSON, Birch Stewart Kolasch & Birch, LLP, Falls Church, VA, argued for cross-appellants. Also represented by EUGENE PEREZ.

Before NEWMAN, O'MALLEY, and TARANTO, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* TARANTO.

Opinion concurring in part and dissenting in part filed by *Circuit Judge* NEWMAN.

TARANTO, *Circuit Judge*.

Cochlear Bone Anchored Solutions AB owns U.S. Patent No. 7,043,040, which describes and claims a bone-anchored hearing aid that transmits soundwaves transcranially from a patient's deaf side to the patient's non-deaf ear. Oticon Medical AB, Oticon Medical LLC, and William Demant Holding A/S (together, Oticon) successfully sought from the Patent and Trademark Office (PTO) two inter partes reviews of, collectively, all claims of the '040 patent under 35 U.S.C. §§ 311–319. In those reviews, the PTO's Patent Trial and Appeal Board concluded that Oticon proved claims 4–6 and 11–12 unpatentable, but did not prove claims 7–10 unpatentable. (Cochlear disclaimed claims 1–3 and 13.) Cochlear appeals the ruling on claims 4–6 and 11–12, while Oticon cross-appeals the ruling on claims 7–10. We affirm the Board's conclusions as to all claims except claim 10, as to which we vacate and remand.

I

A

The '040 patent describes a hearing aid with several parts. One part is a vibration-producing component implanted and mechanically anchored into a patient's skull on the patient's deaf side. '040 patent, col. 2, lines 16–22, 48–55. An external part of the hearing aid, which includes a microphone, picks up sound on the patient's deaf side, processes the sound, and generates vibrations in the implanted part. *Id.*, col. 2, line 44, through col. 3, line 8. Those vibrations are transmitted through the patient's skull to the patient's non-deaf ear, so that the patient's non-deaf ear perceives sound originating from the deaf-ear side. *Id.*

Several additional details discussed in the specification are relevant to the issues before us. The '040 patent notes that high-frequency soundwaves, as they traverse the skull, weaken in strength more than do low-frequency soundwaves; that is, transcranial attenuation is greater for treble than for bass frequencies. *Id.*, col. 2, lines 56–62. The patent suggests that this differential attenuation may be addressed by selectively amplifying treble frequencies relative to bass frequencies. *Id.* In addition, the patent describes the following alternative embodiments of the hearing aid: one with a battery in the external part that powers the internal part through induction, another with a battery in the internal part that is recharged through induction. *Id.*, col. 3, lines 11–24.

Claim 1 of the '040 patent is the independent claim on which all claims now at issue depend, directly or indirectly. It recites:

> 1. A bone-conducting bone-anchored hearing aid apparatus for sound transmission from one side of a patient's head to the patient's cochlea on another side of the patient's head for rehabilitation of unilateral hearing loss, the hearing aid apparatus comprising:
>
> a vibratory generating part arranged to generate vibrations that are mechanically transmitted through the skull bone from a deaf side to the inner ear on the other side of the patient; and
>
> an implantable part operative to mechanically anchor the vibratory generating part, the implantable part being osseointegrated in the patient's skull bone behind an external ear at the deaf side of a patient.

Id., col. 3, lines 29–41. Cochlear statutorily disclaimed independent claims 1 and 13 and dependent claims 2–3 during the inter partes reviews. The claims addressed by the Board and now before us are dependent claims 4–12, all of which are apparatus claims.

Claims 4 and 5 require that the frequency characteristics of the hearing aid are "specifically adapted to transmit vibrations in the skull bone from one side of the skull to the other side" (by incorporation of claim 3) and require that treble frequencies are amplified more than bass frequencies. *Id.*, col. 3, lines 44–53. Claim 6, dependent on claim 1, requires electronic circuitry "to convert a signal from a microphone of the hearing aid to the vibratory generating part from an analog signal to a digital signal." *Id.*, col. 4, lines 1–5. Claims 7–9, dependent on claim 6, all require certain "digital signal processing means" or "signal processing means." *Id.*, col. 4, lines 7–19. Claim 10, dependent on claim 6, requires "directivity means comprising at least one directivity dependent microphone and/or signal processing means." *Id.*, col. 4, lines 20–24. Claim 11, dependent on claim 1, specifies that the implanted part and the vibration-producing part are included in the internal part and that power is transmitted from the external part of the hearing aid to the internal part by induction. *Id.*, col. 4, lines 26–32. Claim 12, dependent on claim 11, adds that the internal part includes a rechargeable battery to be charged by induction from an external power supply. *Id.*, col. 4, lines 33–36.

B

Oticon filed two petitions for inter partes reviews, challenging all claims of the '040 patent. The Board, acting as delegee of the PTO's Director, 37 C.F.R. §§ 42.4, 42.108, initially instituted a review only of claims 1–6 and 11–13. It declined to institute a review of claims 7–10 on the ground that those claims likely are means-plus-function claims

subject to 35 U.S.C. § 112, ¶ 6 (2006),[1] but there is no identified corresponding structure in the specification, without which "the differences between the claimed invention and the asserted prior art cannot be ascertained." J.A. 295. The Board consolidated the two IPR proceedings.

After the Supreme Court issued its decision in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018), the Board added claims 7–10 to the proceedings. It authorized the filing of supplemental briefs on those claims. In the supplemental briefing, the parties agreed to broad constructions for the means-plus-function limitations, namely that the "digital signal processing means" and "signal processing means" limitations include a "digital signal processor" and the "directivity means" limitation includes "a directivity dependent microphone (or directional microphone) and/or a digital signal processor." J.A. 461–63, 476.

The Board proceeded to trial on the following invalidity grounds: claims 4–5 as obvious over Vaneecloo[2] and Carlsson;[3] claims 6, 7, and 9 as obvious over Vaneecloo, Carlsson, and Leysieffer;[4] claim 8 as obvious over Vaneecloo,

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[1] Because of the filing date of the application that issued as the '040 patent, the means-plus-function provision applicable in this case is 35 U.S.C. § 112, ¶ 6, which is now codified, without change material to this case, as 35 U.S.C. § 112(f). *See Zeroclick, LLC v. Apple Inc.*, 891 F.3d 1003, 1006 n.2 (Fed. Cir. 2018).

[2] F.M. Vaneecloo et al., *Prosthetic Rehabilitation of Unilateral Anakusis: Study by Stereo-Audiometry*, 117 Ann. Otolaryngol. Chir. Cervicofac. 410 (2000).

[3] Peder U. Carlsson, Dep't of Applied Electronics, Chalmers Univ. of Tech., Tech. Report No. 195, *On Direct Bone Conduction Hearing Devices: Advances in Transducer Technology and Measurement Methods* (1990).

[4] Can. Patent Pub. No. 2301437 A1.

Carlsson, Leysieffer, and Schaefer;[5] claim 10 as obvious over Vaneecloo, Carlsson, Leysieffer, and Lesinski;[6] claim 11 as anticipated by Hough;[7] and claim 12 as obvious over Hough and Leysieffer.

Vaneecloo describes a clinical study of the "possibilities of prosthetic rehabilitation by semi-implantable bone-anchored hearing aid (BAHA) in two patients with unilateral anakusis."[8] J.A. 783. The study involved surgically implanting a bone-anchored hearing device on a patient's deaf side that transcranially transmits sound received on the deaf side to the patient's non-deaf ear. J.A. 784. The investigators concluded that "the amplification of the high-pitched sounds captured on the anakusis side and perceived by transcranial route by the contralateral ear allowed for a significant rise in sound perception thresholds of frequencies between 1,000 and 4,000 Hz." J.A. 788.

Carlsson discloses the use of a bone-anchored hearing device for the treatment of patients with conductive or sensorineural hearing loss. J.A. 840. Carlsson also discloses a hearing aid fitting process in which the user manipulates the bass and treble frequency controls independently to optimize the device's frequency characteristics for that user. J.A. 819–22.

Leysieffer describes a partially or fully implantable hearing aid system capable of processing or generating signals according to set parameters and converting acoustic signals into electrical signals. J.A. 916, 926. Leysieffer discloses transmitting signals, through inductive coupling,

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[5] U.S. Patent No. 4,729,366.

[6] U.S. Patent No. 5,881,158.

[7] J.V.D. Hough et al., *Long-Term Results for the Xomed Audiant Bone Conductor*, 28 Otolaryngol. Clinics of N. America 43 (1995).

[8] "Anakusis" refers to hearing loss or deafness.

from an external unit to an implanted part. J.A. 917. Leysieffer also describes charging, by inductive coupling, a rechargeable battery cell located in the hearing aid's implanted part. J.A. 925.

Hough describes the Xomed Audiant Bone Conductor device, which uses an alternating electrical current generated by an external processor to electromagnetically vibrate an implanted osseointegrated magnet. J.A. 1097–98. The external processor includes a microphone to pick up sounds on a patient's deaf side, an amplifier, and an electromagnetic coil to vibrate the implanted magnet, which sends vibrations transcranially to a patient's non-deaf ear when activated. J.A. 1098.

In its final written decision, the Board concluded that claims 4–6 and 11–12 are unpatentable on the grounds raised in Oticon's petitions. J.A. 48–86, 89. The Board also concluded that Oticon had not proven claims 7–10 unpatentable, reasoning that the means-plus-function limitations of those claims have no corresponding structure disclosed in the specification, so that the Board could not "ascertain the differences between the claimed invention and the asserted prior art" for those claims. J.A. 16–30, 89.

The Board decided several claim-construction disputes relevant to the issues now before us, relying on the broadest-reasonable-interpretation standard, whose applicability to this case is not in dispute. It ruled that claim 1's preamble phrase "for rehabilitation of unilateral hearing loss," applicable to all claims currently at issue, did not limit the scope of the claims. J.A. 33–35. The Board also considered claim 3's phrase "the frequency characteristics of the apparatus are specifically adapted to transmit vibrations in the skull bone from one side of the skull to the other side," applicable to claims 4 and 5, and determined that frequency characteristic adaptations need not "account for the mechanics of the skull." J.A. 38–41. The Board construed claim 6's "electronic circuitry" limitation, applicable

to claims 6–10, to mean "an analog-to-digital converter." J.A. 31. The Board construed "induction," in claims 11 and 12, to mean "electromagnetic induction," but held that the term did not require the generation of voltage or current in the implanted part. J.A. 41–45.

C

Cochlear timely appealed the Board's determination that claims 4–6 and 11–12 have been proved unpatentable, and Oticon timely cross-appealed the Board's decision that claims 7–10 have not been proved unpatentable. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

We review the Board's compliance with legal standards de novo, *Pride Mobility Products Corp. v. Permobil, Inc.*, 818 F.3d 1307, 1313–14 (Fed. Cir. 2016), and its underlying factual determinations for substantial evidence, *Personal Web Technologies, LLC v. Apple, Inc.*, 848 F.3d 987, 991 (Fed. Cir. 2017). Among the factual determinations in an obviousness analysis are "findings as to the scope and content of the prior art . . . [and] the presence or absence of a motivation to combine or modify with a reasonable expectation of success." *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1364 (Fed. Cir. 2015). A determination of anticipation is a factual finding reviewed for substantial-evidence support. *Dell Inc. v. Acceleron, LLC*, 818 F.3d 1293, 1298 (Fed. Cir. 2016). "We review the Board's claim construction de novo and any underlying factual findings for substantial evidence." *Kaken Pharm. Co. v. Iancu*, 952 F.3d 1346, 1350 (Fed. Cir. 2020).

II

Cochlear challenges several aspects of the Board's unpatentability determinations for claims 4–6 and 11–12. We do not find these challenges persuasive.

A

Cochlear challenges the Board's conclusion that claim 1's preamble phrase "for rehabilitation of unilateral hearing loss" does not limit the scope of the claims and also the Board's rejection of Cochlear's narrowing construction of that phrase as limited to certain profound hearing loss. We reject this challenge at the first step, agreeing with the Board that the phrase is not limiting for the apparatus claims at issue.

"We have treated the effect of preamble language as a claim-construction issue." *Arctic Cat Inc. v. GEP Power Prods., Inc.*, 919 F.3d 1320, 1327 (Fed. Cir. 2019). We have stated that "as a general rule preamble language is not treated as limiting," *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1347 (Fed. Cir. 2012), but "[w]hether to treat a preamble as a limitation is determined on the facts of each case in light of the overall form of the claim[] and the invention as described in the specification and illuminated in the prosecution history," *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1357 (Fed. Cir. 2012) (quotation marks omitted). We have also explained that "[t]hose general formulations have for decades been implemented through a number of more concrete and objective rules." *Arctic Cat*, 919 F.3d at 1327.

"In general, a preamble limits the invention if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quotation marks omitted). The preamble may be limiting to the extent it is "necessary to provide antecedent basis for the body of the claim." *Symantec Corp. v. Computer Assoc. Int'l, Inc.*, 522 F.3d 1279, 1288 (Fed. Cir. 2008); *see TomTom, Inc. v. Adolph*, 790 F.3d 1315, 1323 (Fed. Cir. 2015). But "preamble language merely extolling benefits or features of the claimed invention does not limit the claim scope without clear reliance on those benefits or features

as patentably significant." *Catalina*, 289 F.3d at 809. Further, "[w]e have long ruled that 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." *Arctic Cat*, 919 F.3d at 1328 (quotation marks omitted); *see Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229, 1236 (Fed. Cir. 2017); *Catalina*, 289 F.3d at 808; *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997).

The Board in this case correctly held that the preamble phrase "for rehabilitation of unilateral hearing loss" is not a limitation on the scope of these apparatus claims. J.A. 31–35. The preamble's recitation of "for rehabilitation of unilateral hearing loss" is merely a statement of intended use of the claimed hearing aid. It identifies no structure for the apparatus claimed. Moreover, this use itself is not an inventive or patentably distinct aspect of the claimed invention, as "rehabilitation of unilateral hearing loss" was a conventional use of prior art bone-anchored hearing aids. *See* '040 patent, col. 1, lines 44–61; *Arctic Cat*, 919 F.3d at 1329–30 (preamble phrase "[a] personal recreational vehicle" was not limiting because it merely described conventional, rather than inventive aspects of the claimed invention).

The bodies of the claims contain the only descriptions of the structure for the hearing aid, with no additional structure furnished by the preamble phrase at issue. For example, the body of independent claim 1 identifies the orientation and implantation of the device relative to the patient's head. *See* '040 patent, col. 3, lines 36–37 ("from a deaf side to the inner ear on the other side of the patient"); *id.*, col. 3, lines 39–41 ("the implantable part being osseointegrated in the patient's skull bone behind an external ear at the deaf side of a patient"). The body of the claim also recites the function and position of the implanted "vibratory generating part." *See id.*, col. 3, lines 34–39 ("generate vibrations that are mechanically transmitted through the

skull" and "an implantable part operative to mechanically anchor the vibratory generating part"). These descriptions offer a complete structure such that "for rehabilitation of unilateral hearing loss" adds nothing to the configuration of the claimed device.

The phrase "for rehabilitation of unilateral hearing loss" also is not necessary to provide antecedent basis for the body of the claims. Although the preamble term "a patient" may provide antecedent basis for claim 1's later recitation of "the patient," that is not the preamble language Cochlear argues is limiting. A conclusion that some preamble language is limiting does not imply that other preamble language, or the entire preamble, is limiting. *See TomTom*, 790 F.3d at 1322–23. The language at issue here, which states only an intended use, adds no structural element, and provides no antecedent basis for the body of the claims, is not limiting.

B

Claims 4 and 5, which depend directly or indirectly on disclaimed claim 3, require that "the frequency characteristics of the [bone-anchored hearing aid] are specifically adapted to transmit vibrations in the skull bone from one side of the skull to the other side." Claim 4 further requires that the hearing aid amplifies treble frequencies more than bass frequencies. Claim 5 additionally requires that the amplified "treble frequencies have a frequency greater than 1 kHz."

Cochlear challenges the Board's obviousness determinations for claims 4 and 5 on three grounds. The first argument—that Carlsson teaches away from use in patients with profound hearing loss—is premised on an incorrect assumption that the intended-use language of the preamble is limiting, an assumption we have rejected above. The second argument—that the "specifically adapted to" limitation requires that the frequency characteristics "account for the mechanics of the skull"—and third argument—that

the Board lacked substantial evidence to find that Vaneecloo teaches amplifying treble frequencies more than bass frequencies—are not persuasive for the reasons we now discuss.

Cochlear has not persuasively identified an error in the Board's conclusion that the "specifically adapted to" limitation has its ordinary meaning, with no additional requirement that adaptions be made to frequency characteristics to "account for the mechanics of the skull." J.A. 39–41. In fact, Cochlear has not concretely identified why the Board's ordinary-meaning construction is not the broadest reasonable interpretation.

To the extent that Cochlear is suggesting that the language requires a particular intent or objective of a hearing-aid designer or manufacturer, we reject the suggestion. We have previously held that the claim term "adapted to" generally means "made to," "designed to," or "configured to" perform the stated function, and we have not introduced a subjective element into the construction of the phrase. *See In re Man Machine Interface Techs. LLC*, 822 F.3d 1282, 1286 (Fed. Cir. 2016); *In re Giannelli*, 739 F.3d 1375, 1379 (Fed. Cir. 2014); *Aspex Eyewear*, 672 F.3d at 1349. To the extent that Cochlear is suggesting an objective characteristic of the configuration, it has not shown overbreadth of the Board's ordinary-meaning construction. The claim phrase at issue, in its broadest reasonable interpretation, covers any frequency-characteristic adaption "to transmit vibrations in the skull bone from one side of the skull to the other side." Either Cochlear's proposal is redundant of that language or it is unduly limiting. In neither case is there error in the Board's claim construction.

Cochlear's final challenge to the Board's conclusion about claims 4 and 5 addresses the additional differential-amplification limitations of those claims. This challenge turns specifically on whether there is substantial evidence in the record from which the Board could have determined

that Vaneecloo discloses amplifying treble frequencies more than bass frequencies. We conclude that the Board did have such evidence.

The Board relied on Vaneecloo's disclosure that "the amplification of the high-pitched sounds captured on the anakusis side and perceived by transcranial route by the contralateral ear allowed for a significant rise in sound perception thresholds of frequencies between 1,000 Hz and 4,000 Hz." J.A. 59 (citing J.A. 788). Based on that statement, the Board found that Vaneecloo discloses amplifying treble frequencies more than bass frequencies. *See* J.A. 59–62. Vaneecloo's disclosure explicitly states that the study involved amplification of treble frequencies. J.A. 788. Vaneecloo also notes that "high-pitched sounds reach the ear opposite the source with an attenuation that increases proportionately with the frequency of the sound," indicating that high-pitched sounds must be amplified more than low-pitched sounds. J.A. 783; *see* J.A. 59. Other record evidence further supports the notion that Vaneecloo discloses amplifying treble frequencies more than bass frequencies. The BAHA Classic 300 device available at the time of the Vaneecloo study[9] was capable of adjusting treble and bass frequencies relative to each other. J.A. 1414 ("The low frequency response can be adjusted using the tone control . . . . Turn the tone control [counterclockwise] to decrease the low frequency sound."); J.A. 1443 ("[T]he low-frequency response can be adjusted in order to increase . . . the treble sound relative to the bass."). The Board, therefore, had substantial evidence to conclude that Vaneecloo discloses amplifying treble frequencies more than bass frequencies.

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[9] Cochlear agrees that the BAHA Classic 300 was the bone-anchored hearing aid in existence at the time of the Vaneecloo study. J.A. 58; J.A. 385.

C

Claim 6 requires electronic circuitry that converts an analog signal to a digital signal, which the Board construed as requiring "an analog-to-digital converter." Cochlear does not dispute that the combination of Vaneecloo, Carlsson, and Leysieffer discloses all limitations of claim 6. But Cochlear challenges the Board's finding that a relevant artisan would have been motivated to combine the signal processor disclosed in Leysieffer with the hearing aid disclosed by the combination of Vaneecloo and Carlsson.

We reject that challenge, concluding that the Board's finding is supported by substantial evidence. Oticon's expert, Dr. Popelka, asserted that a relevant artisan would have been motivated to modify the Vaneecloo/Carlsson device to include an analog-to-digital converter in order to obtain the advantages associated with digital processing (*e.g.*, real-time and multi-channel audio signal processing; feedback reduction; more closely matching the needs of the individual patient). J.A. 737–38. Leysieffer itself discusses the benefits of digital signal processing in bone-anchored hearing aids, including adapting for patient-specific circumstances and updating processing software without removing the implanted part of the hearing aid. J.A. 921, 931. In light of that evidence, and the absence of persuasive contrary evidence that the Board had to credit, the Board reasonably found a motivation to combine Leysieffer with Vaneecloo and Carlsson.[10]

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[10] Cochlear additionally argues that the Board did not analyze the motivation to combine references in light of the claim preamble. As discussed above, however, the preamble is not limiting.

D

Claim 11 requires the external part of the hearing aid to transmit power to the internal part by induction. The Board found that Hough's disclosure of an external electromagnetic coil that generates an alternating current, thereby causing the implanted magnet to vibrate, meets the induction limitation. J.A. 78–81 (citing J.A. 1097–98); *see also* J.A. 1098 ("When the current is passed through the external coil . . . alternating electromagnetic fields cause the magnet implanted in the temporal bone to vibrate."). Cochlear challenges the Board's finding that Hough anticipates claim 11, arguing that because there is no voltage or current generated in the internal part of Hough, it is not powered by induction. We reject this challenge.

Cochlear does not challenge the Board's construction of "induction" to mean, without further qualification, "electromagnetic induction." Appellant's Br. 29. Although Cochlear earlier disputed the Board's construction of "power"—which the Board declined to limit to electric power—Cochlear's argument on appeal focuses only on the construction of "induction." Appellant's Br. 29–30; J.A. 41–45. Cochlear does not challenge the Board's understanding of Hough. Instead, Cochlear argues that "electromagnetic induction" necessarily requires the generation of voltage or current in the internal part, a limitation that the Board specifically excluded from its construction of "induction." J.A. 44–45.

We are not persuaded. Cochlear has not established a plain meaning of "electromagnetic induction" (or "power") as requiring a voltage or current on the receiving end. Nor does the '040 patent specification require a particular structure or the generation of voltage or current in the internal part. *See, e.g.*, '040 patent, col. 3, lines 11–14. Particularly for the vibrator, the '040 patent describes the element in only general terms. *Id.*, col. 3, lines 9–11; *see also id.*, col. 2, lines 50–53; *id.*, Fig. 2. We therefore affirm the Board's finding that Hough anticipates claim 11.

E

Claim 12, which depends on claim 11, further requires the external part of the hearing aid to charge, by induction, a rechargeable battery in the internal part. Cochlear does not dispute that the combination of Hough and Leysieffer teaches every limitation of claim 12. Cochlear argues only that the Board did not have substantial evidence to find a motivation to combine Hough with Leysieffer because the internal part in Hough—a magnet—is not powered by a battery.

We disagree. The Board had substantial evidence to find that moving the battery to an internal part of the hearing aid would allow for a smaller and more aesthetically pleasing external part, a benefit that would have motivated a relevant artisan to combine the two references. J.A. 82–85. The prior art specifically notes a patient preference for hearing aids with smaller, more discrete external parts, which can be achieved by moving external elements of the device to the internal part. J.A. 83 (citing J.A. 918–19, 1343); *see also* J.A. 918–19 (visible external parts "stigmatize the wearer and therefore are not willingly worn," and for these devices, "it now seems to be a good idea to design the systems such that they can be completely implanted"). Moving the battery to an internal part reduces the size of the external part even if the internal part itself does not require power, as is the case for Hough.

Cochlear lastly argues that Hough teaches away from using its disclosed device in patients with profound hearing loss. *See* J.A. 1099. Because the preamble is not limiting, and there is therefore no limitation on the type of hearing loss to be treated by the claimed hearing aid, this argument is not persuasive.

III

On cross-appeal, Oticon argues that the Board erred in determining that it could not conduct a prior-art analysis

for claims 7–10 and, on that sole basis, ruling that those claims had not been proved unpatentable. The Board concluded that because these claims contain means-plus-function limitations, without a corresponding structure disclosed in the specification, it could not construe the claims in order to compare the claim requirements with the prior art. We hold that the Board did not err as to claims 7–9, but did err as to claim 10.

A

Where a claim contains a requirement that must be met by any device or process within its scope, and the meaning of that requirement is entirely unknown, the claim cannot be compared to the prior art for purposes of an invalidity analysis, and so that analysis cannot be conducted. *See Samsung Elecs. America, Inc. v. Prisua Eng'g Corp.*, 948 F.3d 1342, 1353 (Fed. Cir. 2020). One such situation can occur when a multi-element claim recites as one required element a means for performing a function but does not recite a structure for performing that function. If the claim is in that format, 35 U.S.C. § 112, ¶ 6, states that the claim scope is defined based on what the specification sets out as corresponding structures for performing the claimed function. 35 U.S.C. § 112, ¶ 6 (claim element defined to mean those structures and equivalents). If the specification fails to recite a corresponding structure, then there is a wholly undefined claim element: the claim has what amounts to an inkblot as a required element of the claim. Such a claim logically cannot be compared to prior art, because an essential claim element has no discernible meaning.

Such a claim is indefinite, *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1351–52 (Fed. Cir. 2015), but that is not the inquiry in an inter partes review, in which the Board may not hold a challenged claim of a patent indefinite. *See* 35 U.S.C. § 311(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2141–43 (2016); *Samsung*, 948 F.3d

at 1350–53. The crucial point for purposes of an inter partes review of issued claims is that, in the situation just described, it is impossible to conduct a prior-art analysis because there is a required claim element without meaning. In this situation, the Board should "conclude that it could not reach a decision on the merits with respect to whether petitioner had established the unpatentability of those claims under sections 102 or 103." *Samsung*, 948 F.3d at 1353.

The Board here properly did just that for claims 7–9. Each of those claims plainly contains at least one *required* means-plus-function claim element for which the specification provides no corresponding structure. In this circumstance, the Board's necessary course of action was to conclude that unpatentability of claims 7–9 could not be shown. We therefore affirm the Board's ruling as to claims 7–9.

Such a necessary rejection of the petitioner's prior-art challenge rests on a deficiency of the patentee's making, not the petitioner's. We have accordingly held, and here reiterate, that "in cases in which the Board cannot reach a final decision as to the patentability of certain claims because it cannot ascertain the scope of those claims with reasonable certainty, the petitioner would not be estopped by 35 U.S.C. § 315(e) from challenging those claims under sections 102 or 103 in other proceedings." *Samsung*, 948 F.3d at 1353 n.3.

B

Claim 10 is different in a crucial respect. It does not contain a *required* claim element in means-plus-function form. Claim 10 recites a "directivity means comprising at least one directivity dependent microphone and/*or* signal processing means in the electronic circuitry." '040 patent, col. 4, lines 20–24 (emphasis added). The use of the disjunctive creates three alternative subsets of claim coverage—a directivity dependent microphone only; signal

processing means only; and a directivity dependent microphone together with signal processing means. The first alternative is independent of the others, and it has a discernible meaning and can be compared to prior art.

The Board correctly held that claim 10 invokes means-plus-function claiming in part, *i.e.*, insofar as it claims a "signal processing means." The Board also correctly held that the specification does not recite a corresponding structure for performing the signal processing function. J.A. 25–27. Oticon does not challenge these holdings. But claim 10, unlike the other means-plus-function claims, also describes a stand-alone alternative to the signal processing means: a directivity dependent microphone, which is a clear structure for performing the claimed directivity means. The Board did not conclude that this alternative (which recites structure in the claim) is even subject to 35 U.S.C. § 112, ¶ 6, let alone that it flunks the requirement of that provision. Rather, it relied entirely on the presence of the signal-processing-means alternatives in the claim to deem a prior-art analysis impossible. J.A. 26–29. That was error.

For present purposes, we may assume that claim 10 is indefinite because it includes what is tantamount to an inkblot as an alternative way of coming within its boundaries. But *Samsung* establishes that indefiniteness of a claim does not always imply inability to conduct a prior-art analysis needed for an inter partes review. *See Samsung*, 948 F.3d at 1352–53, 1355 (remanding for the Board to proceed despite one kind of indefiniteness, based on mixing product and process elements in a claim). The questions are different. Here, even if claim 10 is indefinite, such a conclusion would not imply that it is incapable of being compared to prior art to determine if one of its alternatives is anticipated or would have been obvious on the grounds asserted.

We vacate the Board's ruling as to claim 10 and remand. The Board should consider on remand whether the directivity-dependent-microphone alternative is outside the scope of § 112, ¶6, because it recites a structure (the directivity dependent microphone) that sufficiently corresponds to the claimed directivity means. *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1427–28 (Fed. Cir. 1997) (even if a claim uses the term "means," "where a claim recites a function, but then goes on to elaborate sufficient structure, material, or acts within the claim itself to perform entirely the recited function, the claim is not in means-plus-function format"); *see also Williamson*, 792 F.3d at 1349; *cf. Media Rights Techs., Inc. v. Capital One Fin. Corp.*, 800 F.3d 1366, 1372 (Fed. Cir. 2015). The Board also should consider whether any asserted prior-art challenges render the directivity-dependent-microphone alternative within claim 10 unpatentable, if considered on its own, and whether, if so, claim 10 as a whole is unpatentable on that ground. *See In re Cuozzo Speed Techs., LLC,* 793 F.3d 1268, 1281 (Fed. Cir. 2015); *see also In re Klein*, 987 F.2d 1569, 1570 (Fed. Cir. 1993).

We emphasize that we go no farther in vacating and remanding with respect to claim 10 than to hold that a prior-art analysis is not made impossible, in the context of the "and/or" claim at issue, by the impossibility of such an analysis as to other alternatives in such a disjunctive formulation.

IV

We affirm the Board's decision that claims 4–6 and 11–12 are unpatentable and that claims 7–9 have not been proven unpatentable. We vacate the Board's decision that claim 10 has not been proven unpatentable, and we remand for further proceedings on that claim.

Each party shall bear its own costs.

AFFIRMED IN PART, VACATED IN PART, AND REMANDED

United States Court of Appeals for the Federal Circuit

COCHLEAR BONE ANCHORED SOLUTIONS AB,
Appellant

v.

OTICON MEDICAL AB, OTICON MEDICAL LLC, WILLIAM DEMANT HOLDING A/S,
Cross-Appellants

2019-1105, 2019-1106

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2017-01018, IPR2017-01019.

NEWMAN, *Circuit Judge*, concurring in part, dissenting in part.

I concur in the court's decision concerning claims 7–10. However, the Board erred in its invalidation of claims 4–6, 11, and 12,[1] and my colleagues err in sustaining that ruling.

The invention in United States Patent No. 7,043,040 ("the '040 patent") is a hearing aid for use in single-side

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[1] *Cochlear Bone Anchored Sols. AB v. Oticon Medical AB*, IPR2017-01018, Paper No. 52, at 48–86 (P.T.A.B. Aug. 21, 2018) ("Board Op.").

deafness, or "unilateral hearing loss." Cochlear Bone Anchored Solutions AB ("Cochlear") explains that single-side deafness is usually due to damage to one ear such that the ear cannot perceive sound, and is not remediable by simply increasing amplification to that ear. The experts agreed that there was an unmet need for effective remedy. However, my colleagues find the system in the '040 patent to be obvious, although the system escaped the many persons studying the problem and seeking solution, as seen in the prior art.

In finding the '040 patent's system obvious, the court employs an improper analytic technique. The court first removes major limitations from the claims, and then applies selected pieces of prior art to the residue. This is achieved by holding that the opening clause of all the claims is "not limiting," whereby the claims are freed of critical limitations and are then held to embrace prior art that is excluded from the '040 system by the introductory statement. My colleagues dispose of these limitations by designating the introductory clause as a mere "preamble" that does not limit the claims—although the clause states limitations fundamental to the '040 invention. It is incorrect to remove such claim limitations when they describe substantive aspects of the invention, and the error is compounded when, as here, the court then broadens the residue of the claim into obviousness over prior art that is disavowed by the preamble.

The claim is viewed as a whole

Claims 4–6, 11, and 12 all depend from claim 1, and start with the following clause:

> 1. A bone-conducting bone-anchored hearing aid apparatus for sound transmission from one side of a patient's head to the patient's cochlea on another side of the patient's head for rehabilitation of unilateral hearing loss, ...

The court rules that this entire clause is "not limiting," and thereby opens the claims to prior art that is distinct from the '040 invention, prior art that is distinguished by the limitations in this clause. As stated in *In re Bulloch*, 604 F.2d 1362, 1365 (CCPA 1979), the "introductory claim language . . . is more than a mere statement of purpose; and that language is essential to particularly point out the invention defined by the claims."

This introductory claim language provides the "understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989). The proper analytic method is to determine obviousness of the invention as a whole and the claims as a whole in light of the prior art as a whole. *See In re Gorman*, 933 F.2d 982, 986 (Fed. Cir. 1991) ("[T]he test is whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention."). It is a distortion to hold that the obviousness determination does not include consideration of the introductory words of the claim.

Claims cannot enlarge what is described in the specification, but neither can the claims be redacted to provide a broader focus for prior art. Determination of obviousness (and anticipation) is of the invention that is claimed, with claims that are viewed in light of the specification. *See United States v. Adams*, 383 U.S. 39, 48–49 (1966) ("While the claims of a patent limit the invention, and specifications cannot be utilized to expand the patent monopoly, it is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention.") (internal citations omitted).

The court's analysis produces major changes in the relation of the claimed invention to the prior art; as illustrated in the majority opinion at page 14 n.10, where the court disposes of the obviousness analysis by stating that there is no need to "analyze the motivation to combine

references in light of the claim preamble" because "the preamble is not limiting."

The opinion distorts the '040 patent's invention by stating: "Because the preamble is not limiting, [] there is therefore no limitation on the type of hearing loss to be treated by the claimed hearing aid." Maj. Op. at 16. It is, however, stated throughout the patent documents that the '040 invention is directed to unilateral hearing loss. *See, e.g.*, '040 patent, Abstract ("A hearing aid apparatus is intended for . . . rehabilitation of patients with unilateral hearing loss."); '040 patent, col. 1, ll. 5–11 ("The present invention relates to a hearing aid . . . for rehabilitation of patients with unilateral hearing loss."). This is the invention for which patentability is determined. *See Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333–34 (Fed. Cir. 2003) (the preamble is a statement of the purpose of the invention).

Here, the "specification makes clear that the inventors were working on the particular problem" of an effective treatment for unilateral hearing loss, not on "general improvements" in hearing aids. *Corning Glass*, 868 F.2d at 1257; *see* '040 patent, col. 1, ll. 5–11. The court's exclusion of the "preamble" from the description of the claimed invention underlies the court's entire analysis, and leads to the court's erroneous ruling of invalidity.

The invention described and claimed in the '040 patent is not obvious from the prior art

The Board recognized that the '040 patent's hearing device is not simply a combination of known elements, and stated: "we do not disagree with Patent Owner's contention that the proposed modification would require 'substantially modifying the device.'" Board Op. at 85. However, the Board then itself modified the device by removing the preamble's limitations from the claims.

Recourse to "broadest reasonable interpretation" does not permit an interpretation that is broader than that which is described and claimed. *See Organik Kimya AS v. Rohm & Haas Co.*, 873 F.3d 887, 892 (Fed. Cir. 2017) ("Even under the broadest reasonable interpretation, the Board's construction cannot be divorced from the specification and the record evidence.") (internal quotation marks omitted). That interpretation must be consistent with the specification and the prosecution history, and must be the reasonable interpretation that would be reached by a person of skill in the field of the invention.

For example, there is dispute about the meaning of "induction" in claims 11 and 12. Oticon argues that "induction" should be broadly construed to encompass Hough's magnet, although the experts agreed that induction requires generation of current or voltage in the receiver. The Board, and now this court, hold that claim 11 is anticipated by the Hough device, although the Board recognized that "Hough does not include an internal receiving conductor." Board Op. at 84. The Board held that Hough anticipates claim 11 even though the experts for both sides agreed that Hough's magnet does not serve as a conductor. The court errs in holding that Hough's different system "anticipates" the '040 patent claims. *See MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999) ("anticipation" requires that the invention is described in a single reference disclosing every limitation of the claims).

The question of obviousness includes determining whether the prior art suggests producing the claimed combination and with a reasonable expectation of success. Here, no prior art suggests the combination that is described and claimed in the '040 patent. It appears undisputed that at the time of this invention, transcranial attenuation was not even considered in bone-anchored hearing devices. Reply Br. 21–22 (citing J.A. 464–65 ("[A]t the critical date, [hearing devices] were primarily used to treat conductive hearing loss (CHL), where sound

vibrations are sent to the normal functioning cochlea, not an injured cochlea. . . . TA [transcranial attenuation] was not a consideration. When treating CHL, sound vibrations are not being transmitted to the opposite side of the head (and thus do not need to travel very far within the skull), and therefore TA is not a concern."); J.A. 2352–53, ¶ 21 ("[S]ince sound waves are not needed to travel across the skull to the cochlea on the other side of the head (in the treatment of conductive hearing loss), transcranial attenuation is not an important consideration.").

In sum, the analysis by the Board, and now by my colleagues, is contrary to the laws of obviousness and anticipation. There is no suggestion in the prior art of this new and useful device. *See Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed. Cir. 1985) ("[T]here must be some reason for the combination other than the hindsight gleaned from the invention itself."). Nonetheless, the court here uses the '040 patent's teachings to select various aspects from the prior art, and then combines these selections with the template of the '040 patent, having removed the limitations of the claims' introductory clause. From this flawed analysis, and its flawed conclusion, I respectfully dissent.