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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PETER A. LEWIN, YOUHAN SUNNY, CHRISTOPHER R. BAWIEC, LEONID ZUBKOV, AN NGUYEN, JOSHUA SAMUELS, and ELIZABETH R. PAPAZOGLOU

Appeal 2019-003773
Application 14/241,709
Technology Center 3700

Before MICHAEL J. FITZPATRICK, WILLIAM A. CAPP, and JILL D. HILL, *Administrative Patent Judges.*

HILL, *Administrative Patent Judge.*

DECISION ON APPEAL[1]

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant appeals from the Examiner's decision to reject claims 1, 3–5, 7–9, 11, 12, 14, 15, 21–24, 27, 28, 30, and 31. Final Act. 1. We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

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[1] We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies Drexel University as the real party in interest. Appeal Br. 2.

BACKGROUND

Independent claims 1 and 14 are pending. Independent claim 1, reproduced below, illustrates the claimed invention:

> 1. A device that produces ultrasonic waves at a frequency of 10 kHz to 200 kHz and an acoustic intensity of 0.1 mW/cm^2 to 100 mW/cm^2, for therapeutic treatment comprising:
>
> at least one ultrasound transducer, wherein the ultrasound transducer comprises:
>
> a first flexible cover having a concave configuration;
>
> a second flexible cover having a concave configuration opposing the first cover to form a cavity between said first and second covers, and
>
> a piezoelectric element attached to and positioned between the first and second covers; and
>
> an electronic driving module connected through an electrical matching network and operatively associated with at least one ultrasound transducer to supply an excitation voltage of 20V or less to the piezoelectric element,
>
> wherein the first and second covers are fabricated from a conductive material and a perimeter of the piezoelectric element is bonded to the first and second covers by an adhesive layer formed of a conductive material, and
>
> wherein the electronic driving module comprises an oscillator.

REFERENCES

Name	Reference	Date
Driller	US 4,484,569	Nov. 27, 1984
Kost	US 6,190,315 B1	Feb. 20, 2001
D'Sa	US 6,322,532 B1	Nov. 27, 2001
Puria	US 6,629,922 B1	Oct. 7, 2003
Carazo	US 2007/0041595 A1	Feb. 22, 2007
Unger	US 2009/0209899 A1	Aug. 20, 2009
Mulvihill	US 2010/0292632 A1	Nov. 18, 2010
Castel	US 2011/0040235 A1	Feb. 17, 2011

REJECTIONS[2]

I. Claims 1–5, 8, 9, 11–14, 22, and 24 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Mulvihill, Puria, D'Sa, Carazo, and Unger. Final Act. 5–12.

II. Claim 15 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Mulvihill, Puria, D'Sa, Carazo, Unger, and Kost. Final Act. 12–13.

III. Claims 21 and 23 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Mulvihill, Puria, D'Sa, Carazo, Unger, and Driller. Final Act. 13.

IV. Claim 7, 27, and 28 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Mulvihill, Puria, D'Sa, Carazo, Unger, and Castel. Final Act. 13–14.

[2] Claims 26 and 29, rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, were canceled. *See* Appeal Br. 27 (Claims App.). Because claims 26 and 29 have been canceled, they are no longer rejected under 35 U.S.C. § 103.

V. Claim 30 and 31 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Mulvihill, Puria, D'Sa, Carazo, Kost, and Unger. Final Act. 14–17.

OPINION

Rejection I: Claims 1–5, 8, 9, 11–14, 22, and 24

Claims 1, 2, 4, 8, 9, 11, 13, 14, 22, and 24

Regarding independent claims 1 and 14, the Examiner finds that Mulvihill discloses the device as claimed, except for (1) the piezoelectric element being "bonded to the first and second covers by an adhesive layer formed of a conductive material," and (2) a "driving signal of 20V or less." Final Act. 5–7. The Examiner finds, however, that Puria discloses using both a conductive and a non-conductive adhesive in a transducer depending on desired performance (Final Act. 6 (citing Puria Figs. 3A-B; 12:1–10, 12:23–32)), and concludes that it would have been obvious to modify Mulvihill to use a conductive adhesive layer (*id.* at 7 (citing Puria 12:1–6 (explaining that the ability to use either conductive or non-conductive adhesive provides "the ability to use either the adhesive . . . or conductive end caps . . . for introducing the electrical signal to the piezoelectric substrate.")).

The Examiner further finds that the claimed excitation voltage of "20V and less is a designer choice that only require[s] ordinary skill in the art." *Id*. The Examiner relies on D'Sa and Carazo to teach using an excitation voltage of 20V or less. *Id.* (citing D'Sa 3:60–67 ("The voltage (rms) of the applied signal is generally from about 30V to 300V, although lower voltages are preferred.")); *see also* Carazo ¶¶ 31, 92, 112 (Table 5) (showing performance of a transducer with an input of 2V, 10V, and 20V)).

The Examiner relies on Unger to establish that 20V is a known excitation voltage for ultrasound for drug delivery. *Id*. (citing Unger ¶ 81 ("An ultrasonic signal (typically of 40 kHz) is generated . . . by way of the signal generator . . . providing a peak-to-peak voltage of 20 V to the ultrasonic transducer 104. This provides an acoustic flux of approximately 200 mW/cm^2.").

Appellant argues claims 1, 2, 4, 8, 9, 11, 13, 14, 22, and 24 as a group. We select claim 1 as representative. Claims 2, 4, 8, 9, 11, 13, 14, 22, and 24 stand or fall with claim 1.

Appellant argues that, although Mulvihill discloses the output frequency and acoustic intensity recited in the preamble of independent claim 1 and the body of independent claim 14, it requires 200V to produce such output, which is ten times the "20V or less" recited in claims 1 and 14. Appeal Br. 11, 12 (citing Mulvihill ¶ 69). Indeed, Appellant argues, "none of the cited references discloses a device that produces [the claimed output] using an excitation voltage of 20 V or less." *Id.* at 12. Appellant notes that Unger uses an excitation voltage of 20V and outputs an acoustic intensity of $200mW/cm^2$, or double the acoustic intensity recited in the claims (*id*. (citing Unger ¶ 81)), and Carazo uses an excitation voltage of 2–20V and "operates at 0.1–8 kHz which is [less than the] claimed range of 10-200 kHz" (*id.* (citing Carazo Tables 4–6)). Regarding D'Sa, Appellant notes that it only discloses an excitation voltage "from about 30V to 300V, although lower voltages are preferred where a suitably responsive piezoelectric material is used." *Id*.

Similarly, Appellant argues that the Examiner erred in concluding that a skilled artisan would have modified Mulvihill to use the input voltages of

D'Sa, Carazo, and Unger. Appeal Br. 13. According to Appellant, the Examiner (1) incorrectly treats the excitation voltage, frequency, and acoustic intensity of "ultrasonic transducers independently when, in fact, they are interrelated," and (2) fails to consider "very significant structural differences [among] the prior art ultrasonic transducers and the effect that these structural differences will have on the excitation voltage, frequency, acoustic intensity, and displacement of the ultrasonic transducers." *Id*.

Regarding combinability of Mulvihill and D'Sa specifically, Appellant contends that a skilled artisan would consider the structural differences among the prior art transducers, and the interrelationship of the inputs and outputs, when considering modifying Mulvihill, and "would not have a reasonable expectation of successfully generating ultrasonic waves having the claimed frequency and acoustic intensity by modifying the transducer of Mulvihill based on the teachings of D'Sa." *Id.* at 14–16 (citing Lewin Declaration[3] for the proposition that different transducers required different excitation voltages).

Regarding combinability of Mulvihill and Carazo specifically, Appellant argues that a skilled artisan would not have used Carazo's 20V input with Mulvihill's transducers, because the structure and intended use of the transducer of Mulvihill's micro-patch are different from the structure and intended use of the transducer of Carazo's hearing aid, and "the media that transmit the generated ultrasound waves" differ — bone conduction for Carazo and soft tissue conduction for Mulvihill." Appeal Br. 16. According to Appellant, Carazo's excitation voltage is disclosed solely for its "thunder

[3] Declaration under 37 C.F.R. § 1.132 of inventor Peter Lewin, filed December 12, 2018.

actuator 12 that is shown and described in Fig. 7b of Carazo," and one skilled in the art would understand that different transducers "may require different excitation voltages." *Id.* at 17 (citing Carazo ¶¶ 106–107).

Regarding combinability of Mulvihill and Unger specifically, Appellant argues that Unger discloses, *inter alia*, using a 20V excitation voltage generating an ultrasonic signal having an acoustic intensity of approximately 200 mW/cm^2 (double the upper limit of the acoustic intensity of claim 1), which "clearly supports the conclusions of Dr. Lewin that structural differences in transducers [generate] different acoustic intensities even when using the same excitation voltage of 20 V." Appeal Br. 18 (citing Unger Fig. 3).

While we have considered these arguments regarding the combinability of Mulvihill with each of D'Sa, Carazo, and Unger, we find the arguments unavailing at least because they consider the combinability of Mulvihill with each of the secondary references separately, rather than considering the combined teachings of the combined references as a whole, and how those teachings come together with the knowledge of a skilled artisan at the time of the invention to render the claimed invention obvious. Additional analysis of the Examiner's reasoning is set forth below.

The Examiner responds that Appellant's arguments are not directed to device structure, and that

> • Mulvihill discloses a transdermal micro-patch intended to transmit ultrasonic waves into soft tissue to aid transport of fluid into the tissue;
>
> • D'Sa, also dealing with transdermal applications, supplements Mulvihill's teachings by suggesting that an ordinary artisan would be motivated to use low excitation

> voltages, preferred for obvious reasons, where a suitably responsive piezoelectric material is used [col.3, 11.60-67];
>
> • Carazo teaches that excitation voltages of 20V or lower can be used with piezoelectric ceramic materials that are not excluded by Appellant's disclosure

Ans. 14–15.

Further, the Examiner contends, D'Sa "discloses explicitly that the excitation voltage depends on the material used." *Id.* at 15. According to the Examiner, using "better energy saving material" could lower the excitation voltage required to output the claimed frequency of 10 kHz to 200 kHz and an acoustic intensity of 0.1 mW/cm2 to 100 mW/cm2 to 20V, and Carazo discloses that such an "energy saving material" exists. *Id*.

Regarding Appellant's argument that Mulvihill's transdermal micro-patch has different structure and intended use than Carazo's hearing aid, the Examiner counters that such an intended use argument "is not persuasive because the device claim does not have any particular structural limitations . . . exclusive to either a hearing aid or transdermal patch," and an "ultrasound transducer is [used] to transmit ultrasound [for] a myriad of applications," including medical uses as disclosed in both Mulvihill and Carazo. Ans. 15.

Appellant replies that, because the claims recite an ultrasound frequency of 0.1–8 kHz, the claim includes limitations that are exclusive to a transdermal patch. *See* Reply Br. 5.

Appellant's argument, that the claimed frequency limits the intended use of the device to transdermal patches, lacks evidentiary support. Further, intended use is a functional limitation that does not differentiate an apparatus claim from the prior art. *See Hewlett-Packard Co. v. Bausch & Lomb Inc.*,

909 F.2d 1464, 1469 (Fed. Cir. 1990) ("apparatus claims cover what a device is, not what a device does"). Still further, Appellant has not provided evidence of the relevant structural difference between Mulvihill's transdermal micro-patch and Carazo's hearing aid. Also, as explained above, in the argument, Appellant's argument regards only the disclosure of Mulvihill and Carazo, rather than the combined teaching of the applied references and the knowledge of a skilled artisan.

To counter Dr. Lewin's opinion that the driving signal of D'Sa is not directly applicable to Mulvihill's transducer because structural differences in the transducers significantly affect transducer displacement, the Examiner contends that Appellant's own disclosure indicates that figuring out the dimensions and other characteristics of a transducer for a given input and output is within the knowledge of a skilled artisan for a given piezoelectric ceramic material. Ans. 16 (citing Spec. ¶ 29 ("[P]iezoelectric element 14 preferably has a thickness, an overall dimension and a piezoelectric coefficient sufficient to enable production of low intensity and low pressure amplitude ultrasound waves from a minimal amount of excitation voltage," and "can be constructed from any suitable piezoelectric material, including piezoelectric ceramics, such as lead zirconate titanate and hard lead zirconate titanate.")). The Examiner further contends that, for cymbal transducers, "[i]t is the material that dictates the driving voltage as pointed out by D'Sa." *Id.* at 17 (citing D'Sa 3:60–67 ("lower voltages are preferred where a suitably responsive piezoelectric material is used")). The Examiner continues that:

> The working principle of the cymbal transducer is to simply use voltage to oscillate the end caps (see appellant's Fig. 4a, stage 0 and stage 1; element 26). With a more flexible material, less

> voltage is required to oscillate the end caps. Mulvihill's device and appellant's device have the same structure using the same treatment intensity and frequency, but have a different driving voltage. The only reasonable explanation is that they use a different material as evidenced by D'Sa.

Id. Then, the Examiner continues, "Carazo's teach[es] using piezoelectric ceramic materials to allow use of more energy efficient 20V or less." *Id*.

Appellant replies that the Examiner's reasoning is incorrect, unsupported by evidence, and contradicted by Appellant's Specification and the Lewin Declaration. Reply Br. 2. According to Appellant, the Specification of the present invention discloses, instead, that transducer energy efficiency and transducer output depend not just on the material, but on "the material, geometry and dimensions of piezoelectric element 14, the material, structure (material, shape, cavity depth, outer diameter and apex diameter) and acoustic impedance of covers 16, 18, the volume and shape of cavity 20, how transducers 12 are mounted to housing 50[,] and the electrical matching network." *Id*. (quoting Spec. ¶ 37). Thus, Appellant argues, the Examiner's contention "that a more energy efficient piezoelectric material could lower the driving voltage of the D'Sa device to 20V or less . . . is pure speculation . . . and inconsistent with the teachings of D'Sa and the facts and evidence presented in [Appellant's Specification] and the Lewin Declaration." *Id*. at 3–5. Appellant further argues that Carazo does not explicitly disclose a material that would lower the driving voltage of D'Sa to 20V or less. *Id*.

Appellant also argues that using paragraph 29 of the instant Specification to support the Examiner's conclusion of obviousness indicates

that the Examiner employed impermissible hindsight in the rejection. *See* Reply Br. 6–7.

While using Appellant's own disclosure to provide a reason for combining the prior art can be indicative of impermissible hindsight use, here, the Examiner cites Appellant's Specification as evidence that a skilled artisan would understand how to combine the thickness, overall dimension, and piezoelectric coefficient (indicative of material selected) to "enable production of low intensity and low pressure amplitude ultrasound waves from a minimal amount of excitation voltage." Ans. 16. We discern no error on the Examiner's reliance on Appellant's Specification as evidence of the knowledge of a skilled artisan at the time Appellant's invention. Indeed, Appellant left any and all working combinations of these characteristics to the knowledge of a skilled artisan. *See* Spec. ¶ 37 ("[E]nergy efficiency of transducer 12 is dependent in part upon the material, geometry and dimensions of piezoelectric element 14, the material, structure and acoustic impedance of covers 16, 18, the volume and shape of cavity 20, how transducers 12 are mounted to housing 50 and the electrical matching network. Additionally, the generated ultrasound intensity, pressure amplitude and frequency is dependent upon the material, thickness and diameter of piezoelectric element 14, and the material, shape, cavity depth, outer diameter and apex diameter of first and second covers 16, 18."). To now say the exact combination(s) required to obtain the claimed transducer output from the claimed transducer input is beyond the knowledge of a skilled artisan is disingenuous.

Further, the prior art relied on by the Examiner makes clear that it is both material and geometry that are relevant to transducer efficiency and

performance. Indeed, Mulvihill discusses transducer geometry and material selection generally, and incorporates a disclosure of specific cymbal-shaped flextensional transducers by reference. *See* Mulvihill ¶¶ 18–20 and 41 (incorporating by reference US 5,729,077 entitled Metal-Electroactive Ceramic Composite Transducer and US 6,665,917 entitled Method of Fabricating a Planar Pre-stressed Bimorph Actuator).

Puria also discloses a cymbal-type flextensional transducer, and discusses the differing geometries and materials for its transducers. *Id.* at 4:40–50 ("metal-shell or plastic-shell, end caps" and "[t]he shape of the shell to a large extent determines the mechanical advantage"), 6:6–13 ("he actuator may be round or of a prismatoid shape," "[t]he end caps . . . may be made of a superelastic alloy, a metal alloy, or a polymeric material," and the size of the . . . actuator is less than 5 mm but . . . is not limited to this dimension"), 8:44–67 (the substrate is "selected from piezoelectric cermaics such as PZT, PLZT, PMN, PMN-PT" and "the substrate itself may be a single layer or . . . a multi-layer composite," "[t]he substrate typically is generally circular, although the substrate is not limited such a configuration"), 9:1–5 ("configuration of the end caps, to a large extent, determines the displacement amplification"), 9:24–30 ("the invention does not exclude the use of ceramic, polymer, or other types of piezo elements" and can include "several types of piezo-metal or piezo-plastic composite actuators"), and 10:61–65 ("[the] angle of the side panels . . . may be altered to, e.g., variously maximize the size of the planar diaphragm . . or enhance the mechanic advantage of the planar diaphragm"). Puria, thus, informs us that the geometry and material of transducers has an impact on their performance that would be known and appreciated by a skilled artisan.

Given this disclosure in Puria, we agree with the Examiner that, although "none of the cited references discloses a device that produces [the claimed output] using an excitation voltage of 20 V or less," a skilled artisan would understand how to select and refine the material and geometry of a transducer to provide an output appropriate for its intended use with a desired excitation voltage. Appeal Br. 12.

D'Sa discloses transducers that transmit ultrasonic waves into soft tissue, and is directed to a more efficient transducer. *See, e.g.*, D'Sa 2:41–47. D'Sa discloses preferred piezoelectric materials, such as a piezoceramic discussed in Mulvihill, and discloses that the excitation voltage can be 30V – 300V "although lower voltages are preferred where a suitably responsive piezoelectric material is used." *Id.* at 3:36–37, 3:60–67. While Puria informs us that it was known to select and refine the material and geometry of a transducer to provide an output appropriate for the transducer's intended use for a given excitation voltage, D'Sa informs us that lower excitation voltages are preferred and depend on the piezoelectric material used.

Carazo also discloses a piezoelectric flextensional transducer that outputs a range of 10 kHz – 200 Khz. Carazo, Abstract, ¶ 30–31. The transducer can be a cymbal type having, e.g., a piezoelectric ceramic with a metal shell. Carazo, ¶ 88, 92. Carazo supplies an excitation voltage of less than 20V to transducers having varied housing materials, although the data collected and disclosed is not specifically for a cymbal-type transducer as used in Mulvihill. *Id.* ¶ 112 (Table 5). Thus: (1) Puria informs us that it was known to combine the material and geometry of a transducer to provide an output appropriate for its intended use with a given excitation voltage; (2) D'Sa informs us that lower excitation voltages are preferred and depend on

the piezoelectric material used; and (3) Carazo informs us that a 20V excitation voltage can be used with a piezoelectric ceramic, which is not excluded from the materials of Appellant's invention. Appellant has not informed us specifically why the data of Carazo's Table 5, cited by the Examiner, would not be understood to a skilled artisan to apply to a cymbal-type transducer.

Further, the Examiner's findings and conclusions underlying the determination that a skilled artisan would understand how to design the material and geometry of a transducer to have the desired input and output is based on the Examiner's understanding that the excitation voltage and the frequency and intensity of a transducer are interrelated, and we therefore are not persuaded by Appellant's argument that the Examiner incorrectly treats the excitation voltage and the frequency and acoustic intensity of "ultrasonic transducers independently when, in fact, they are interrelated," or the Appellant's argument that the Examiner fails to consider "very significant structural differences [among] the prior art ultrasonic transducers and the effect that these structural differences will have on the excitation voltage, frequency, acoustic intensity and displacement of the ultrasonic transducers." Appeal Br. 13. It is exactly this understanding and consideration that leads to the Examiner's (and to our) determination of obviousness in this case.

Although Appellant's intended use argument might otherwise imply an argument that the teachings of Puria and Carazo are not applicable to Mulvihill's transducer because the prior art references are non-analogous art, Appellant does not refute the Examiner's determination that the field of endeavor of the prior art references is ultrasound transmission for medical

uses.[4] Final Act. 18; *see also* Ans. 15. We discern no error in the Examiner's determination. All of the devices are directed to ultrasound transmission into the human body and, even if the frequency and acoustic intensity desired for hearing aids may differ from the frequency and acoustic intensity desired for ultrasound into other body tissue, the Examiner's determines that the ability to design a cymbal transducer to achieve a given input and output within the level of ordinary skill in the art, and Appellant has not provided factually-supported reasoning that persuades us that a skilled artisan would not consider teachings for a hearing aid relevant to transducers for other body tissue.

In the Reply Brief, Appellant argues for the first time that "Mulvihill does not include an electrical matching network as required by all of the claims of the present application." Reply Br. 8. This argument was not raised in the Appeal Brief, is not responsive to any argument raised in the Examiner's Answer, and good cause has not been shown. *See* 37 C.F.R. § 41.41(b)(2). We will not consider this argument because it was not timely raised, and we have not received the Examiner's position on the proper construction of this term and whether the prior art reads on such construction.

For the reasons explained above, we sustain the rejection of claim 1. Claims 2, 4, 8, 9, 11, 13, 14, 22, and 24 fall with claim 1.

[4] Although the Examiner does not use the term "field of endeavor," because an explicit challenge of the references as non-analogous was not set forth, we understand the Examiner to have made such a finding.

Claim 3

Dependent claim 3 recites "a conductive epoxy" bonding "the first and second covers to the piezoelectric element," and each of the first and second covers comprising an apex having "a circular configuration." The Examiner finds that Mulvihill discloses conductive epoxy adhesive. Final Act. 6, 12 (citing Mulvihill ¶¶ 26, 38, 58, 65–66, Figs. 2–4, 6). The Examiner finds that both Mulvihill and Puria disclose an apex with a circular configuration. Final Act. 10 (citing Mulvihill ¶¶ 29–31, Figs 1, 3d ("element 2"); and Puria Figs.1, 2B, 2C, 4E ("cap 160–162 is [a circular] apex" and "flextensional transducer 132 has circular apex")). The Examiner asserts that apex shape is a design choice, which we consider to be the stated motivation for using Puria's circular apex in Mulvihill's transducer. *Id*.

Appellant argues that the Examiner erred in finding that (1) Mulvihill's adhesive is a conductive epoxy, and (2) Mulvihill's transducer apex is circular. Appeal Br. 20. Appellant also argues that the Examiner has not established that one skilled in the art would replace Mulvihill's transducer apex with Puria's circular end caps 160, 162 "with an expectation of successfully arriving at the present invention including being able to meet the claimed frequency, acoustic intensity and excitation voltage limitations," and "in view of the structural differences between the devices of Mulvihill and Puria and the conclusions of Dr. Lewin regarding the importance of such structural differences." *Id*.

Regarding the claimed conductive epoxy adhesive, the Examiner responds that Puria discloses using conductive epoxy adhesive, and Mulvihill explicitly discloses using adhesive to secure portions of its device. *See* Ans. 19 (citing Puria Fig. 3A, 12:1–10; Mulvihill ¶ 38). Appellant

replies that Puria never uses the term epoxy as claimed, instead only disclosing a conductive adhesive. Reply Br. 10.

Regarding conductive epoxy, Puria discloses a cymbal transducer with the substrate adhered to the end caps using either a conductive or non-conductive adhesive. *See* Puria 9:55–59, Fig. 1A. One example of an adhesive used in Puria is "MASTER BOND" (*id.* at 9:55–59), which we understand to be an epoxy adhesive. Thus, Puria disclose an epoxy adhesive. Puria discloses that selection among conductive or non-conductive adhesives "places the ability to use either the adhesive . . . or conductive end caps . . . as the site for introducing the electrical signal to the piezoelectric substrate." *Id.* at 12:28–31. For this reason, we are not persuasive that the prior art lacks disclosure of a conductive epoxy adhesive.

Regarding the circular apex, the Examiner responds that the rejection does not suggest replacing Mulvihill's transducers 2 with Puria's end caps 160, 162, because the Examiner finds that both Mulvihill and Puria disclose circular apexes — though it is clearer to see that Puria's device has a circular apex. Ans. 18.

Appellant replies that it is the Examiner's initial burden to establish that Mulvihill's transducer has a circular apex, and the Examiner has failed to establish that Mulvihill's apex is circular, which is the case because Mulvihill's transducer apex is neither shown nor described. Reply Br. 9. We agree with Appellant's contention on this point. Puria, however, discloses a circular apex.

Regarding modifying Mulvihill to include Puria's circular apex, Appellant argues that the Lewin's Declaration "demonstrates that structural differences will influence the frequency, acoustic intensity and excitation

voltage of the device," and Appellant's Specification "clearly indicates that [apex shape] influence[s] the frequency, acoustic intensity and excitation voltage of the device." *Id.* at 10.

However, a circular apex was known from the disclosure of Puria. Further, it is Puria that, as explained above, informs us that it was known to select and refine the material and geometry of a transducer to provide an output appropriate for the transducer's intended use with a given excitation voltage. Thus, we agree with the Examiner's determination that a skilled artisan could apply Puria's circular apex teaching to Mulvihill, particularly given Puria's suggestion of using a circular apex, and in an effort to design a transducer having a desirable input/output performance.

For these reasons, we sustain the rejection of claim 3.

Claim 5

Dependent claim 5 recites that the "distance between the piezoelectric element and the apex of the first cover is 0.01 mm to 5 mm." We understand this claimed distance to be shown in Appellant's Figure 4(c). The Examiner does not find this teaching in the prior art of record, asserting instead that Mulvihill's device "is a small device similar to a bandage therefore it would have been obvious to one of ordinary skill in the art at the time of the invention that a distance between the piezoelectric element and the apex of the first cover is 0.01 mm to 5 mm," which would be "a design choice that does not offer operational advantage" or novelty. Final Act. 10.

Appellant argues that the Examiner's assertion is incorrect, because the claimed distance "defines one dimension of the cavity which generates the ultrasonic output of the device," and "changes to this distance would be

expected to influence the operating parameters of this device since this will alter the structure of the device." *See* Appeal Br. 20–21.

The Examiner responds that Appellant's claimed distance is obvious because "distance influences the operating parameters of the device [by altering] the structure of the device." Ans. 18.

Appellant replies that the Examiner's positions contradict themselves, because the Examiner first says that the claimed distance is "a design choice that does not offer operational advantage," and then says that the claimed distance influences the operating parameters of the transducer. Reply Br. 11.

The Examiner considers the claimed distance to be a design choice. Final Act. 10. Even if the claimed distance (an aspect of the transducer's geometry) influences the operating parameters of the transducer, Appellant has not alleged or explained why such influence of transducer operating parameters defines a "novel or unexpected result." *See In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990) (where the difference between the claimed invention and the prior art is some range within the claims, "the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range"). Indeed, Appellant's Specification identifies no such unexpected results and, as explained above, Puria informs us that it was generally known to select and refine the material and geometry of a transducer to influence operating parameters of the transducer, implying that the result of the claimed distance would have been expected. We find no evidence in Appellant's disclosure of unexpected results attributed to the claimed distance.

Claim 12

Dependent claim 12 recites the device being "a flexible patch or bandage that can be worn by a patient" and weighing "200 grams or less." The Examiner finds that Mulvihill's device "is a flexible patch or bandage that can be worn by a patient." Final Act. 11 (citing, e.g., Mulvihill, Abstract ("transdermal micro-patch"), ¶ 23 ("The invention can be integrally manufactured, including lightweight and compact power electronics and control mechanisms, so as to have a small footprint to minimize the tissue area affected by the device and to minimize discomfort to the wearer, thus providing a compact, wearable solution.")). The Examiner asserts that, although Mulvihill does not disclose its device weighing 200 grams or less, Mulvihill's patch "is a micro patch therefore it would have been obvious to one of ordinary skill in the art at the time of the invention that it is very light and [weigh] 200 grams or less." *Id*.

Appellant argues that Mulvihill fails to disclose a device weighing 200 grams or less, and "it is pure speculation that a working device could be built based on the teachings of Mulvihill which weighs 200 grams or less." Appeal Br. 21. Appellant further argues that, although Mulvihill discloses a micro-patch, Mulvihill's device "includes a reservoir 3, a pump 4 and a circuit 5, [] flextensional transducers and wiring for these transducers," which "would be expected to contribute to the weight of the Mulvihill device" and are not accounted for by the Examiner's assertion. *Id*.

The Examiner responds that, based on this logic, Appellant's device would weigh more than 200 grams, because Appellant's device also includes "a reservoir, a pump, a circuit, a plurality of flextensional transducers and wiring for these transducers." Ans. 20. According to the Examiner, if Appellant's device can include all of the components and weigh 200 grams

or less, "then it would be reasonable to assume" Mulvihill's patch also weighs 200 grams or less, and it would have been obvious that Mulvihill's micro-patch "should be very light weight — similar to a bandage." *Id*.

Appellant replies that "claim 12 does require a driving module [recited in claim 1] and thus these six elements which are all part of the driving module of Mulvihill need to be counted in the device weight for the Mulvihill device." Reply Br. 11–12. Appellant contends that the claimed device is "so much lighter than Mulvihill" because its driving voltage is lower and "thus can be generated using a lightweight power source." *Id.* at 12. According to Appellant, "[o]ne reason that the driving voltage of the device of claim 12 is so low is the inclusion of a matching network, which is not part of the Mulvihill device." *Id*.

Again, Appellant's argument regarding the import of the electrical matching network in rendering the claims patentable over the prior art was not raised in the Appeal Brief, is not responsive to an argument raised in the Examiner's Answer, and good cause has not been shown for delayed presentation of the argument. *See* 37 C.F.R. § 41.41(b)(2). Therefore, we will not consider this argument because it was not timely raised, and we have not received the Examiner's position on the proper construction of this term, whether the prior art reads on such construction, its influence on device weight. Such influence is not set forth in Appellant's Specification. *See* Spec. ¶¶ 37–38, and 44.

We note, however, that Mulvihill recognizes device weight as a result effective variable in stating that the invention can include "lightweight and compact power electronics and control mechanisms, so as to have a small footprint to minimize the tissue area affected by the device and to minimize

discomfort to the wearer, thus providing a compact, wearable solution." Mulvihill ¶ 23. Here, the mere carrying forward of Mulvihill's concept of a lightweight, wearable device performing the same function by substantially the same process "is not such an invention as will sustain a patent." *See In re Williams*, 36 F.2d 436, 438 (CCPA 1929) ("It is a settled principle of law that a mere carrying forward of an original patented conception involving only change of form, proportions, or degree, or the substitution of equivalents doing the same thing as the original invention, by substantially the same means, is not such an invention as will sustain a patent, even though the changes of the kind may produce better results than prior inventions."). For this reason, we sustain the rejection of dependent claim 12.

Rejections II–V: Claims 7, 15, 21, 23, and 27, 28, 30, and 31

Appellant makes no argument that claims 7, 15, 21, 23, and 28 are patentable if claims 1 and 14, from which they depend, are not patentable over Mulvihill, Puria, D'Sa, Carazo, and Unger. Thus, for the reasons explained above regarding Rejection 1, we sustain the rejection of claims 7, 15, 21, 23, and 28.

Claims 27, 30, and 31

Dependent claim 27 recites a method of wound treatment using the device of claim 1, "wherein the device is positioned against an epidermal tissue of the patient proximate to a site of the wound to achieve a therapeutic effect." Claims 30 and 31 depend from claim 27.

Appellant argues that none of the prior art relied on by the Examiner discloses wound treatment. Appeal Br. 22. According to Appellant, Mulvihill and Castel disclose "transdermal administration of fluids," D'Sa

discloses "a sonophoresis device," Carazo discloses "a hearing aid," and Unger discloses "a storage device and has no therapeutic purpose." *Id*.

The Examiner responds that Mulvihill discloses ultrasound wound treatment. Ans. 20 (citing Mulvihill Abstract, ¶¶ 4, 6, 23) ("deliver[ing a] drug by ultrasound into the wound is wound treatment by ultrasound mediated therapy"). The Examiner further responds that "any ultrasound device capable of generating the claimed operating ranges would affect treatment." *Id*.

Appellant replies that the Examiner does not appreciate that the claimed ultrasound *mediated* therapy requires that ultrasound "bring about the wound therapy." Reply Br. 12. Appellant contends Mulvihill's wound treatment is instead brought about by its drug, not ultrasound. According to Appellant, while it is true that an ultrasound device capable of generating the claimed operating range would affect wound treatment, the prior art does not disclose affecting wound treatment with ultrasound, only the present invention appreciates ultrasound as a wound treatment therapy, and therefore a conclusion that such use is obvious must be "based on impermissible hindsight." *Id.* at 12–13.

We decline to require that *in vivo* testing substantiate the Examiner's finding that Mulvihill discloses wound treatment. Further, this "bringing about" argument was not raised in the Appeal Brief, is not responsive to an argument raised in the Examiner's Answer, and good cause has not been shown. *See* 37 C.F.R. § 41.41(b)(2). Therefore, we will not consider this argument because it was not timely raised, and we have not received the Examiner's position on the proper construction of this limitation and whether Mulvihill reads on such construction. It seems unlikely that the

language of claim 27 requires that Mulvihill explicitly disclose that the ultrasound aspect of its treatment is what "brings about" wound healing.

For this reason, we sustain the rejection of claims 27, 30, and 31.

DECISION

The Examiner's rejections are affirmed as to all of the pending claims.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–5, 8, 9, 11–14, 22, 24	103(a)	Mulvihill, Puria, D'Sa, Carazo, Unger	1–5, 8, 9, 11–14, 22, 24	
15	103(a)	Mulvihill, Puria, D'Sa, Carazo, Unger, Kost	15	
21, 23	103(a)	Mulvihill, Puria, D'Sa, Carazo, Unger, Driller	21, 23	
7, 27, 28	103(a)	Mulvihill, Puria, D'Sa, Carazo, Unger, Castel	7, 27, 28	
30, 31	103(a)	Mulvihill, Puria, D'Sa, Carazo, Kost, Unger	30, 31	
Overall Outcome			**1, 3–5, 7–9, 11, 12, 14, 15, 21–24, 27, 28, 30, 31**	

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

AFFIRMED