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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CHANGFANG ZHU, DONGCHUL LEE, and
KERRY BRADLEY

Appeal 2019-005324
Application 13/902,754
Technology Center 3700

Before CHARLES N. GREENHUT, BENJAMIN D. M. WOOD, and
ANNETTE R. REIMERS, *Administrative Patent Judges*.

GREENHUT, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner's decision to reject claims 12, 15–17, 19–23, 27, and 29–33. *See* Non-Final Act. 1. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

¹ We use the term “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as Boston Scientific Neuromodulation Corporation. Appeal Br. 2.

CLAIMED SUBJECT MATTER

The claims are directed to a combination electrical stimulation and low-level laser therapy. Claim 12, reproduced below, is illustrative of the claimed subject matter:

12. A method of treating a patient with an ailment, comprising:
conveying electrical energy to a first natural neuronal element and a second natural neuronal element, thereby modulating the first and second natural neuronal elements to treat the ailment; and
conveying low-level laser energy having a wavelength in the range of 600nm-2500nm to the first natural neuronal element, thereby modulating the first natural neuronal element to decrease a side-effect otherwise caused by the modulating of the first natural neuronal element by the electrical energy.

REFERENCES

The prior art relied upon by the Examiner is:

Name	Reference	Date
Wagner '053	US 2008/0046053 A1	Feb. 21, 2008
Wagner '905	US 2013/0053905 A1	Feb. 28, 2013
Wells	WO 2011/150430 A2	Dec. 1, 2011

REJECTION

Claims 12, 15–17, 19–23, 27, and 29–33 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wells, Wagner '053,² and Wagner '905.³ Non-Final Act. 3.

² “Wagner” elsewhere in the record.

³ “Wagner2” elsewhere in the record.

OPINION

Claims 12, 15–17, 19–23, and 34–37 are argued as a group (Appeal Br. 5–8) for which claim 12 is representative under 37 C.F.R.

§ 41.37(c)(1)(iv).

The Examiner implies the subject matter of claim 12 would have been obvious over Wells alone but, according to the Examiner, the Wagner references are cited as additional evidence as to the level of skill in the art and to expedite prosecution. Non-Final Act. 3–6. The main argument of Appellant is as follows:

The effects of Wells cited on pages 4–5 of the Office Action, as well as the effects cited from Wagner[’053] and Wagner[’905], all appear to be primary effects (i.e., directed to treatment of an ailment), not side-effects. Accordingly, none of the cited references address using low-level laser energy to modulate the first neuronal element to decrease a side-effect of caused [sic] by the modulation using electrical energy, as recited in claim 12.

Appeal Br. 6. Thus, it is the “side-effect” language of claim 12 that Appellant relies heavily on in an effort to distinguish over the prior art.

There is not, and cannot reasonably be, any dispute that Wells discloses the conveyance of both electrical and low-level laser energy to trigger a nerve action potential (NAP) *in vivo*. Non-Final Act. 3 (citing Wells para. 268). Appellant does not raise any issues with the Examiner’s reliance on Wells concerning conveying electrical energy to “first” and “second” neuronal elements. *See* Non-Final Act. 3 (citing Wells para. 272). Nor does Appellant raise any issues concerning the Examiner’s reliance on Wells for the specific laser energy wavelength recited. *See* Non-Final Act. 4 (citing Wells para. 269). Lastly, Appellant does not dispute that the triggering of NAPs in Wells is “to treat an ailment.” Indeed, Wells clearly

discusses that the main objective of triggering the NAPs relates to ailment mitigation. Paragraphs 14–17 of Wells discuss this in the context of spinal cord injuries in particular. Paragraph 18 of Wells goes on to describe other ailments that may be treated by generating NAPs via optical or electrical stimulation or inhibition:

Besides such spinal-cord injuries, there are numerous other nerve injuries and pathologies that need treatment. Thus, there is a need to provide therapy (e.g., through stimulation of physiological signals in the patient such as nerve action potentials (NAPs)) that restores such sensations (signals towards the brain) to persons having such injuries, as well as nerve stimulation and/or inhibition for treatment of pain, obesity, epilepsy, depression, and the like. There is also a need to provide therapy that restores motor-nerve (muscle-control) signals from the brain towards muscles or prostheses (through NAP stimulation, inhibition, or both), for motor control as well as treatment of incontinence, irregular heart rhythms, tremors or twitches, and the like.

Wells para. 18 (cited at Non-Final Action 4).

In the Background section of the Specification, Appellant acknowledges diseases and disorders for which electrical stimulation has proven therapeutic:

- cardiac conditions (e.g., arrhythmias)
- chronic pain syndromes
- angina pectoralis
- incontinence
- refractory chronic pain syndromes
- movement disorders and epilepsy
- paralyzed extremities in spinal cord injury
- various headaches, including migraine headaches, cluster headaches, and cervicogenic headaches
- heart failure

- obesity
- asthma
- diabetes
- constipation

Spec. para. 3. Appellant further acknowledges that laser or optical stimulation has demonstrated success in treating pain (Spec. para. 6) and that “low-level laser energy at a wavelength of 600–900nm suppresses the activity of neurons” (Spec para. 7).

As can be readily observed from the preceding paragraphs, Wells sought to employ combination electrical and optical therapy to treat many of the same ailments that Appellant also sought to treat.

Wells describes a challenge associated with electrical stimulation (ES):

One disadvantage of using electrical stimulation is that the electrical signal applied to stimulate one nerve fiber will generally stimulate a plurality of surrounding nerve fibers (even nerve fibers in other fascicles than the fascicle containing the nerve of interest) to also trigger NAP signals in those other nerve fibers:

...

neuromodulation applications such as hand-grasp, sensory-stimulation applications for artificial prostheses, and control of autonomic functions such as cardiac rate via Vagus-nerve stimulation, require, in some cases, selection of at most one fascicle and even greater sub-fascicular spatial selectivity (i.e., selection of a single axon or just a few axons but not all the axons in the single fascicle) than is typically possible using electrical stimulation alone, such that separate signals are delivered to different axons within one fascicle.

Wells paras. 2–3. More specifically, Wells explains:

Because electrical current spreads in the body, most if not all ES-based neural prostheses wind up *stimulating other nerves in the area besides the intended target* (e.g. fine movements cannot be

made with a motor prosthesis, and multiple sensations, such as touch and temperature, *may be felt incorrectly* from a sensory feedback device). Furthermore, the presence of a stimulation artifact can *obfuscate signals elsewhere along the nerve*, and it also precludes stimulating and recording electrical nerve activity in the same location, as needed for a closed-loop sensorimotor limb prosthesis.

Wells para. 51 (emphasis added).

Appellant, albeit more briefly, describes a problem very similar to that described by Wells:

electrical neural modulation may compromise selectivity due to the spread of current.

Spec. para. 18.

because electrical energy is relatively unfocused, the right DR nerve fiber may be inadvertently stimulated, thereby causing a side-effect (e.g., motor movement or painful sensations).

Spec para. 113 (cited at Ans. 9).

There does not appear to be any dispute that, in the context of claim 12, “side-effect” generally refers to some additional, perhaps unintended or undesirable, result of the electrical energy modulating the first natural neuronal element beyond the result primarily intended. Although the examples do not necessarily rise to the level of lexicographic *definitions* of the recited term “side-effect,” they are instructive. Reading the claim in light of the Specification requires us to make an effort to include these examples within the meaning we afford to the recited term “side-effect” absent good reasons not to do so. *See, e.g., Vitronics Corp. v. Conception, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1997) (claim interpretation excluding the preferred embodiment is rarely, if ever, correct and would require highly persuasive evidentiary support).

As emphasized above in the quoted portion of paragraph 51 of Wells, Wells also considers “side-effects” of the treatment, such as incorrect sensations, signal obfuscation, and most similar to the principal side effects discussed in Appellant’s Specification of “[inadvertent] motor movement” or “painful sensations,” Wells describes “stimulating other nerves in the area besides the intended target.” Wells expressly indicates in the parenthetical immediately after mentioning excessive stimulation that such stimulation may result in additional (i.e., not sufficiently “fine”) motor movements. Although not expressly stated in this portion of Wells, we think one skilled in the art would also understand that nerve stimulation exceeding that intended may also result in pain. *See In re Jacoby*, 309 F.2d 513, 516 (CCPA 1962) (A skilled artisan must be presumed to know something about the art apart from what the references expressly disclose.). As Wells mitigates problems essentially the same as those mitigated by Appellant with Wells’s laser treatment technique, we think it is fair to regard Wells’s technique as including “conveying low-level laser energy. . . thereby modulating the first natural neuronal element to decrease a side-effect otherwise caused by the modulating of the first natural neuronal element by the electrical energy” as required by claim 12. *See Non-Final Act. 4.*

The Examiner also articulates an even broader view of Wells in that many of the ailments discussed in Wells, can themselves, in appropriate circumstances, be considered side-effects. *Non-Final Act. 4–5; Ans. 9–10.* There is substantial merit to the Examiner’s position in this regard as well. Again, *skill* is an attribute that must be attributed the hypothetical person described in 35 U.S.C. § 103(a). *In re Sovish*, 769 F. 2d 738, 743 (Fed. Cir. 1985). If a medical provider used Wells’s technique to treat a primary ailment among those listed as examples, and a secondary ailment, or “side-

effect,” was induced which was among those listed by Wells, we agree with the Examiner that it would have been obvious to a professional in the medical arts to also use Wells’s technique to treat the secondary ailment or “side-effect.”

The main point of divergence between Appellant’s *disclosed* technique and Wells’s is that Appellant provides the laser stimulation in an inhibitory manner to “thereby decreas[e] the excitability of the right DR nerve fiber that may otherwise be inadvertently be stimulated by the conveyance of the electrical energy from the neuromodulation lead 12(1)” Spec. paras. 113–114. The cited embodiment of Wells, on the other hand, teaches decreasing side-effects by applying *sub-threshold* electrical stimulation and *additional* focused laser stimulation to trigger a NAP:

The electrical-stimulation signal and the optical-stimulation signal are each at a level that is substantially sub-threshold (i.e., almost all of the time (i.e., at least 90%) they will not trigger a NAP) if either is applied alone, but when applied together (either simultaneously or sufficiently close to one another in time), the combination of electrical- and optical-stimulation signals is sufficient to trigger a NAP (i.e., almost all of the time (i.e., at least 90%) the combination will trigger a NAP).

Wells para. 270 (cited at Non-Final Act. 4).

Appellant does not apprise us of any language, and no language is apparent, in claim 12 that necessarily introduces this distinction into the claim. “The invention disclosed in [Appellant’s] written description may be outstanding in its field, but the name of the game is the claim.” *In re Hiniker Co.*, 150 F. 3d 1362, 1369 (Fed. Cir. 1998). Limitations not appearing in the claims cannot be relied upon for patentability. *In re Self*, 671 F.2d 1344, 1348 (CCPA 1982).

We think the foregoing discussion suffices to establish that the subject matter of claim 12 would have been obvious over the teachings of Wells. Although perhaps not necessary for purposes of claim 12, the Examiner, citing Wagner '905 or "Wagner2" goes on to discuss, how one skilled in the art would have understood electrical and laser energy could be employed in an excitatory or inhibitory way. Non-Final Act. 6. The Examiner's findings in this regard are consistent with the, albeit brief, suggestion in Wells that stimulation, inhibition or both could be employed in Wells's method:

In some embodiments, the method provides therapy that restores motor-nerve (muscle-control) signals from the brain towards muscles or prostheses (through NAP stimulation, inhibition, or both), for motor control as well as treatment of incontinence, irregular heart rhythms, tremors or twitches, and the like.

Wells para. 122. Wagner '905 provides additional and more specific evidence that, in addition to knowing how to add stimulatory energies as Wells does, the skilled artisan would also have known how to combine stimulatory and inhibitory energies to arrive at a desired stimulation:

The methods and devices of this disclosure involve providing a first type of energy to a region of tissue, in which the first type is provided in an amount that inhibits cellular function within the region of tissue, and providing a second type of energy to the region of tissue, in which the second type is provided in an amount that facilitates cellular function within the region of tissue, wherein the combined effect stimulates cellular function within the tissue.

Wagner '905 para. 43 (cited at Non-Final Act. 6).

We think the Examiner's reliance on Wagner '905 suffices to cement the Examiner's conclusion of obviousness with respect to claim 12, to the extent these additional teachings of Wagner '905 are even necessary to support the Examiner's rejection of claim 12. In any case, this teaching of

Wagner '905 addresses the more specific modulation aspect of claim 27 that “only a portion of action potentials . . . is conveyed . . . to the second target side” (Appeal Br. 10–11) and of claim 29 where “action potentials are blocked at the second target site” (Appeal Br. 11–12). Appellant makes similar arguments concerning claims 27 and 29 as those addressed above with regard to claim 12. Appeal Br. 10–12. The only additional argument attacks the Examiner’s failure to reproduce the specific claim language in question regarding claims 27 and 29. Appeal Br. 10–12. As alluded to above regarding claim 12, the Examiner appears to have reached a conclusion of obviousness, and articulated reasoning in support thereof, based on what is arguably an overly narrow reading of claim 12.⁴ However, in doing so, the Examiner sufficiently demonstrated the obviousness of the subject matter defined by claims 27 and 29 as well, despite not reproducing the specific language therefrom. We think Appellant was provided with adequate notice as to the basis for the Examiner’s rejection of claims 27 and 29 based on the Examiner’s discussion in the Non-Final Action. *See In re Jung*, 637 F. 3d 1356, 1363 (Fed. Cir. 2011).

In light of the issues raised for our review, to sustain the Examiner’s rejection of claims 12, 27 and 29, we see no need to cite or discuss any further evidence from Wagner '503, which the Examiner regards as merely further demonstrating the level of skill in the art.

⁴ Of course, addressing *more* than is required according to a claim’s broadest reasonable scope does not constitute reversible error in the context of an obviousness rejection. *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 419–20 (2007) (“What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103.” *KSR*, 550 U.S. at 419).

Claims 33 and 37 are argued as a group (Appeal Br. 12–13) for which claim 33 is representative. These are the only other claims for which separate arguments are presented. Appellant’s arguments quote a portion of the Examiner’s analysis addressing claim 33 and assert that it is incomplete. “Filing a Board appeal does not, unto itself, entitle an appellant to *de novo* review of all aspects of a rejection.” *See Ex Parte Frye*, 94 USPQ2d 1072, 1075 (BPAI 2010)(precedential)(citations omitted). “[T]he Board will not, as a general matter, unilaterally review those uncontested aspects of the rejection.” *Id* at 1075–76 (citations omitted). The only specific language of claim 33 to which Appellant draws our attention relates to “on different nerve fibers of the vagus nerve.” Appeal Br. 13 (emphasis omitted). Appellant argues that neither Wagner reference mentions the vagus nerve. Appeal Br. 13. However, it is Wells the Examiner relies on regarding such subject matter. Non-Final Act. 8. Wells clearly indicates the disclosed technique could be applied to the vagus nerve. Wells paras. 3, 86–89 (cited at Non-Final Act. 7). The remaining aspects of the method set forth in claim 33 are discussed above. Wells’s failure to expressly use the vagus as the subject of treatment in the specific examples given does not undermine a rejection predicated on 35 U.S.C. § 103(a). Just as “a person of ordinary skill often will be able to fit the teachings of multiple patents together like pieces of a puzzle,” (*KSR*, 550 U.S. at 420) a person of ordinary skill will be able to fit the teachings arising from different parts of the same reference together in a similar manner, particularly where the reference itself suggests doing so.

CONCLUSION

The Examiner’s rejection is AFFIRMED.

DECISION SUMMARY

Claim(s)	35 U.S.C. §	Basis/Reference(s)	Affirmed	Reversed
12, 15–17, 19–23, 27, 29–33	103(a)	Wells, Wagner '053, Wagner '905	12, 15–17, 19–23, 27, 29–33	

TIME PERIOD FOR RESPONSE

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

AFFIRMED