



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/302,498	12/14/2005	Stig Ollmar	5808-0105PUS1	1227
127226	7590	10/31/2016	EXAMINER	
Birch, Stewart, Kolasch & Birch, LLP P.O. Box 747 Falls Church, VA 22040-0747			NGUYEN, HUONG Q	
			ART UNIT	PAPER NUMBER
			3736	
			NOTIFICATION DATE	DELIVERY MODE
			10/31/2016	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte STIG OLLMAR, ULRIK BIRGERSSON,
PETER ABERG, INGRID NICANDER,
and THIERRY CORMAN

Appeal 2014-006128
Application 11/302,498
Technology Center 3700

Before JOHN C. KERINS, ANNETTE R. REIMERS, and
JAMES J. MAYBERRY, *Administrative Patent Judges*.

MAYBERRY, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Stig Ollmar et al. (Appellants) seek our review under 35 U.S.C. § 134 of the Examiner's Final rejection of claims 1, 6–20, 25–28, and 33–43. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

CLAIMED SUBJECT MATTER

The claims are directed to a medical apparatus and method for determining biological conditions using impedance measurements. Spec. 1, ll. 5–10. Claims 1, 20, and 28, are independent. Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. A medical apparatus for the diagnosing of a diseased condition of the skin of a subject, comprising:
 - an electrically conducting probe including a plurality of electrodes, each electrode comprising a base substrate and a plurality of micro-needles, wherein said probe is adapted to be placed against a surface of the subject such that said micro-needles penetrate the stratum corneum, wherein said medical apparatus is adapted to initiate an impedance measurement session including passing an electrical current through the electrodes to obtain values of skin impedance, and use reference data to determine whether the obtained impedance values indicate the diseased condition,
 - said micro-needles being integrally formed with said substrate and arranged in a laterally spaced relationship apart from each other and having a length being sufficient to penetrate the stratum corneum, said micro-needles having a substantially triangular cross-section parallel to the base substrate along an entire length thereof, and said micro-needles being arranged with at least one oblique surface extending from a tip thereof to the base substrate such that the cross-section parallel to the base substrate tapers continuously along the entire length thereof from the base substrate to the tip, and
 - the substantially triangular cross-section at the bottom of said micro-needles having two equal sides with a length of s_1 and a third side with a length of b_1 , wherein s_1 is between 20 μm and 200 μm , and b_1 is between 20 μm and 200 μm .

Br. A-1, Claims App.

REFERENCES

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

Park	US 2002/0082543 A1	June 27, 2002
Allen	US 2002/0138049 A1	Sept. 26, 2002
Kenan	US 2003/0078482 A1	Apr. 24, 2003
Brenneman	US 2003/0236543 A1	Dec. 25, 2003
Yuzhakov	US 2005/0209565 A1	Sept. 22, 2005
Ollmar	EP 1 600 104 A1	Nov. 30, 2005

REJECTIONS

I. Claims 1, 6–20, 25–28, and 33–42 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

II. Claims 1, 6–18, 20, 25–28, 33–39, and 43 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ollmar, Brenneman, Park, Allen, and Yuzhakov.

III. Claims 19 and 40–42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ollmar, Brenneman, Park, Yuzhakov, Allen, and Kenan.

ANALYSIS

Rejection I

Independent claims 1, 20, and 28 each require an electrode of an electrically conducting probe to comprise micro-needles, with the “micro-needles having a *substantially* triangular cross-section parallel to the base substrate” of the electrode. *See* Br. A-1–A-6, Claims App. (emphasis

added). The Examiner determines that the term “substantially” is a relative term that renders the claims indefinite. Final Act. 2. The Examiner finds that “the [S]pecification does not provide a standard for ascertaining the requisite degree [attributable to the term ‘substantially’], and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention thus rendering the metes and bounds of the invention unclear.” *Id.*

Appellants contend that the Manual of Patent Examining Procedure (MPEP) expressly permits the use of the term “substantially.” Br. 13 (referencing MPEP § 2173.05(b)). Appellants argue that the Examiner’s rejection ignores the Patent Office’s policy, as reflected in the MPEP, that the term “substantially” is not indefinite. *Id.*

Appellants further contend that “the term ‘substantially’ is disclosed in the [S]pecification.” Br. 13 (referencing Spec. 6, ll. 32–33, which reads: “each of the micro-needles is arranged with a substantially triangular cross-section”). Appellants also identify the disclosure at page 11, lines 17–19 of the Specification, which describes Figures 1a, 1b, 2a, and 2b and states “[t]he dimensions b_1 and s_1 of the micro-needle will be substantially constant along the height h_1 and will taper continuously in a direction from the surface of the base substrate 12 along the height h_2-h_1 .” *Id.* Appellants argue that “[i]n describing the relationship between the sides of the cross-section which include the term ‘substantially,’ the [S]pecification makes reference to the drawings where one can see the relationship between the sides of the cross-section.” *Id.*

Appellants finally argue that the Examiner’s position seems to require Appellants to provide a precise definition of the term “substantially,” which is not required by the case law. Br. 14.

Appellants' arguments do not inform us of Examiner error. As Appellants recognize, "the term 'substantially' is a descriptive term commonly used in patent claims to 'avoid a strict numerical boundary to the specified parameter.'" *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367 (Fed. Cir. 2001). Although we agree with Appellants that the term "substantially" is not *per se* indefinite, "[w]hen a 'word of degree' is used [in a claim], [we] must determine whether the patent provides 'some standard for measuring that degree.'" *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1378 (Fed.Cir.2015).¹ "Claim language employing terms of degree has long been found definite where it provided enough certainty to one of skill in the art when read in the context of the invention." *Id.* In addition, "[t]he degree of precision necessary for adequate claims is a function of the nature of the subject matter." *Id.* at 1382

We agree with the Examiner that Appellants' Specification fails to provide a standard for measuring the degree associated with the term "substantially triangular." Appellants' reliance on the disclosure in the Specification at page 6, lines 32–33 is unavailing. This disclosure merely mimics the claim language—stating that each micro-needle has a substantially triangular cross-section—and provides no further measure of what constitutes "substantially triangular."

¹ This statement of the law is consistent with the MPEP. *See* MPEP § 2173.05(b). Contrary to Appellants' characterization, the MPEP does not provide a policy that the term "substantially" in a claim is definite. Instead, it provides that "[t]erms of degree are not necessarily indefinite." *Id.* As the MPEP makes clear, "when a term of degree is used in the claim, the examiner should determine whether the specification provides some standard for measuring that degree." *Id.*

Appellants' reliance on the disclosure at page 11, lines 17–19 of the Specification is equally unavailing. This disclosure provides that the side lengths of the triangle forming the triangular cross-section of the micro-needle remain substantially constant from the base substrate of the micro-needle to a height “h1” above the base substrate. *See* Spec. 11, 17–19; Fig. 1a. As provided in this disclosure, the length of the two sides s1 and third side b1 do not necessarily remain absolutely constant from the base substrate of the micro-needle to a height “h1” above the base substrate. However, even if one or more of the lengths change, the shape of the cross sectional area of the microneedle would remain a triangle. Tellingly, Figures 1b and 2b, the only illustrations of the cross-section of a micro-needle, depict needle cross-sections that are exactly triangular in shape. *See id.*, Figs. 1b, 2b.

Appellants fail to identify any disclosure in the Specification that indicates what is meant by a cross-section that is “substantially” triangular. For example, would a cross section depicted in Figures 1b and 2b, but with corners that are rounded at the intersection of the sides instead of pointed, be “substantially” triangular? Would a cross section with one or more of the corners removed and replaced with a short line segment, thus forming a four-, five-, or six-sided polygon be “substantially” triangular? We find that the Specification does not disclose a standard to answer these questions.

Similarly, Appellants do not offer any evidence to support a finding that, although the Specification does not provide a standard for measuring the degree associated with the term “substantially,” a person having ordinary skill in the art would understand what the term “substantially” means in the context of the claims. *Cf. Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1335 (Fed. Cir. 2010) (noting that, during prosecution of the claim at

issue, the patentee relied on a declaration to overcome an indefiniteness rejection concerning the term “substantially”). We agree with the Examiner that an artisan of ordinary skill would not understand the scope of the invention of claims 1, 20, and 28 without a standard for measuring the degree associated with the term “substantially” in the Specification. *See* Answer 2. The nature of the subject matter—a polygon-shaped cross-section of a micro-needle—does not lend itself to an understanding of the term “substantially.”

The Examiner also rejects claims 11, 12, 15–17, 26, 27, 38, and 43 for using the term “about.” Final Act. 2. As with the term “substantially,” the Examiner determines that the term “about” is not defined in the claims. *Id.* The Examiner finds that the Specification does not disclose a standard for measuring the degree associated with the term “about” and that a person having ordinary skill in the art would not understand the scope of the claims without such a standard. *Id.* Appellants provide the same arguments with respect to the term “about” as they made with respect to the term “substantially.” *See* Br. 13–14.

We determine that Appellants have the better argument for this issue. “The use of the word ‘about’ avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technologic and stylistic context.” *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995). In each of the rejected claims, the term “about” is used to modify a numerical value. Although we agree with the Examiner that the Specification does not provide a standard for measuring the degree associated with the term “about,” we find that, in the stylistic context that the term is used (modifying a numerical value), an artisan of ordinary skill

would understand that the term “about” means within a small variation of the modified value, such as to allow for manufacturing tolerances.

Accordingly, for the reasons above, we sustain the Examiner’s rejection of independent claims 1, 20, and 28 under 35 U.S.C. § 112, second paragraph, as being indefinite for using the term “substantially.” We also sustain the Examiner’s rejection of claims 6–19, 25–27, and 33–42, which depend, directly or indirectly, from one of claims 1, 20, and 28. We do not sustain the Examiner’s further rejection of claims 11, 12, 15–17, 26, 27, 38, and 43 under 35 U.S.C. § 112, second paragraph, as being indefinite for using the term “about.”

Rejection II

Independent claims 1, 20, and 28 each recite, in relevant part, “the substantially triangular cross-section at the bottom of said micro-needles having two equal sides with a length of s_1 and a third side with a length of b_1 .” *See* Br. A-1–A-6, Claims App. The Examiner relies on Yuzhakov for teaching the above quoted subject matter, finding that Yuzhakov “teach[es] that it is [] well known in the art for analogous microneedles with triangular cross sections to have specifically isosceles triangle configurations (at least two equal sides).” Final Act. 5 (referencing Yuzhakov ¶ 24).

Appellants contend that the micro-needle discussed in paragraph 24 of Yuzhakov has a star-shaped cross-section, not a cross-section of an isosceles triangle, that is, a triangle with at least two equal sides. Br. 16. As Appellants explain, although each blade of Yuzhakov’s micro-needle 900 has a cross-section of an isosceles triangle, the entire micro-needle has a star-shaped cross-section. *Id.* Appellants argue that the Examiner fails to

explain why a person of ordinary skill in the art would take the limited teaching of the shape of part of a micro-needle to modify Ollmar's micro-needle. *Id.* at 16–17. That is, if an artisan of ordinary skill did modify Ollmar's micro-needle based on the teachings of Yuzhakov's micro-needle 900, then Yuzhakov's teachings would yield a micro-needle with a star-shaped cross-section, not a triangular cross-section. *Id.*

The Examiner responds that Yuzhakov is used for the limited teaching of a triangular cross section with two equal sides, as Brenneman, Park, and Allen are relied on for the triangular cross-section of the micro-needle. Answer 3.

We determine that Appellants have the better argument. “Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Here, the Examiner fails to articulate a persuasive reason, supported by a rational underpinning, why a person having ordinary skill in the art would modify Ollmar's micro-needle to form a micro-needle with a cross-section of an isosceles triangle, based on Yuzhakov's teaching of a micro-needle with a star-shaped cross-section, with each blade of the star having a cross-section of an isosceles triangle. The Examiner recognizes that Yuzhakov's micro-needle has a star-shaped cross-section, yet fails to persuasively explain why an artisan of ordinary skill would look to the shape of a single blade of Yuzhakov to modify the triangular cross-sectioned micro-needle of the combined teachings of Ollmar, Brenneman, Park, and Allen. *See* Answer 3.

For the reason above, we do not sustain the Examiner's rejection of claims 1, 6–18, 20, 25–28, 33–39, and 43 under 35 U.S.C. § 103(a) as being unpatentable over Ollmar, Brenneman, Park, Allen, and Yuzhakov.

Rejection III

In rejecting dependent claims 19 and 40–42, the Examiner relies on Yuzhakov for disclosing the subject matter requiring “the substantially triangular cross-section at the bottom of said micro-needles having two equal sides with a length of s_1 and a third side with a length of b_1 ” of independent claims 1 and 20, from which claims 19 and 40–42 ultimately depend. *See* Final Act. 7. Accordingly, for the reason discussed above in connection with our analysis of Rejection II, we do not sustain the Examiner's rejection of claims 19 and 40–42 under 35 U.S.C. § 103(a) as being unpatentable over Ollmar, Brenneman, Park, Yuzhakov, Allen, and Kenan.

DECISION

We affirm the Examiner's rejection of claims 1, 6–20, 25–28, and 33–42 under 35 U.S.C. § 112, second paragraph, as being indefinite.

We reverse the Examiner's rejection of claims 1, 6–18, 20, 25–28, 33–39, and 43 under 35 U.S.C. § 103(a) as being unpatentable over Ollmar, Brenneman, Park, Allen, and Yuzhakov.

We reverse the Examiner's rejection of claims 19 and 40–42 under 35 U.S.C. § 103(a) as being unpatentable over Ollmar, Brenneman, Park, Yuzhakov, Allen, and Kenan.

Appeal 2014-006128
Application 11/302,498

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

AFFIRMED