



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.
13/131,506	08/11/2011	James L. Ratcliff	70878.00100	6202
20322	7590	07/01/2021	EXAMINER	
SNELL & WILMER L.L.P. (Main)			SIMMONS, CHRIS E	
400 EAST VAN BUREN			ART UNIT	PAPER NUMBER
ONE ARIZONA CENTER			1629	
PHOENIX, AZ 85004-2202			NOTIFICATION DATE	DELIVERY MODE
			07/01/2021	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):

IPDOCKET@swlaw.com
chauff@swlaw.com
dgiancaterin@swlaw.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JAMES L. RATCLIFF, LEE E. KIRSCH,
JESSICA K. WARD DYKSTRA, WILLIAM E. COOLEY,
GARY ARMITAGE, ROBERT ASHLEY, and
ESMERALDA ANN GARCIA

Appeal 2020-006130¹
Application 13/131,506
Technology Center 1600

Before DONALD E. ADAMS, FRANCISCO C. PRATS, and
RACHEL H. TOWNSEND, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant² appeals from the Examiner's decision to reject claims 44–46 and 49–60. We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

¹ Although Appellant asserts that there are no related appeals (*see* Appeal Br. 3), Appeal 2020-002938 (Application 13/115,815; decision entered Jan. 28, 2021) involved claimed subject matter similar to that involved in the present appeal.

² We use the word Appellant to refer to “applicant” as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as Micropure, Inc. Appeal Br. 2.

CLAIMED SUBJECT MATTER

Appellant's invention is directed to oral rinses that contain stabilized chlorine dioxide and sodium fluoride.

Appellant's claim 44, the only independent claim on appeal, is representative of the appealed subject matter and reads as follows:

44. An oral rinse composition for enhancing tooth remineralization, comprising:
- a. stabilized chlorine dioxide *that remains stable in the composition*, the stabilized chlorine dioxide capable of reacting with acidic elements of oral biofilms to produce chlorine dioxide gas;
 - b. sodium fluoride; and
 - c. a pharmaceutically acceptable buffer effective at establishing an effective pH range of the composition from about 6.0 to about 7.4 for maintaining the stability of the chlorine dioxide in the composition;

wherein the stabilized chlorine dioxide and the sodium fluoride in combination are more effective at enhancing tooth remineralization and reducing tooth demineralization than either of the stabilized chlorine dioxide or the sodium fluoride alone.

Appeal Br. 18 (emphasis added to claim limitation at issue).

REJECTION(S)

The following rejections are before us for review:

(1) Claims 44–46 and 49–60 under 35 U.S.C. § 112(b) or 35 U.S.C. § 112 (pre-AIA), second paragraph, as being indefinite (Ans. 3–4); and

(2) Claims 44–46 and 49–60 under 35 U.S.C. § 103 as being unpatentable over the Christopfel,³ Oxyfresh C,⁴ and Jensen,⁵ as evidenced by Hill.⁶ Ans. 4–11.

INDEFINITENESS

The Examiner's Rejection

The Examiner determines that the recitation in Appellant's claim 44, “stabilized chlorine dioxide that remains stable in the composition” renders claim 44 indefinite “because the claim does not provide a discernable boundary on what provides the functional characteristic to the stabilized chlorine dioxide (SCD).” Ans. 3. In particular, the Examiner determines that, although “there are multiple ways to help stabilize chlorine dioxide, it is unclear which of those ways are encompassed by the claim.” *Id.* The Examiner reasons as follows:

For example, it is not clear whether the functional characteristic (i.e., “remains stable in the composition”) is due to the addition of some other structure (such as pH modifiers, stabilizers, etc.), absence of destabilizing agents (such as stannous chloride), other features of the composition (such as specific pH ranges) encompassed by the claim, or whether the claim is limited to compositions that have functional characteristic due to a sequence of steps by which it is made or by some other means, or a certain combination of these.

Id. at 3–4.

³ US 6,325,997 B1 (issued Dec. 4, 2001).

⁴ “Oxyfresh C” (“Fluoride Kit.” Oral Health Care. Oxyfresh Worldwide, Inc. http://web.archive.org/web/20080509170508/http://oxyfresh.com/dental/rinse_fluoride.asp. 10/23/2007).

⁵ US 2005/0084551 A1 (published Apr. 21, 2005).

⁶ US 2015/0017107 A1 (published Jan. 15, 2015).

The Examiner also finds that the Specification “does not provide a clear explanation of what constitutes ‘remaining stable in the composition’.” Ans. 4. In particular, the Examiner finds that the Specification “may be interpreted differently by different individuals. One may interpret this to mean that as long as there is some amount of chlorine dioxide in the composition at any given point in time, the SCD ‘remains stable in a composition’.” *Id.* The Examiner finds that “[a]nother may interpret this to require that none of the chlorine dioxide can be altered in any way after 12 months or more of storage.” *Id.* The Examiner reasons, therefore, that a skilled artisan “is not apprised of the metes and bounds of the claimed invention.” *Id.*

Analysis

The Supreme Court has stated that “a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig, Insts., Inc.*, 572 U.S. 898, 901 (2014) (internal quotations omitted); *see also id.* at 910 (“The definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable.”).

Thus, as our reviewing court has explained, a claim does not comply with 35 U.S.C. § 112, second paragraph, “when it contains words or phrases whose meaning is unclear.” *In re Packard*, 751 F.3d at 1310, 1314 (Fed. Cir. 2014) (approving, for pre-issuance claims, the standard from MPEP § 2173.05(e).); *see also Ex parte McAward*, Appeal 2015-006416, 2017 WL 3669566, at *5 (PTAB Aug. 25, 2017) (precedential) (adopting the approach for assessing indefiniteness approved by the Federal Circuit in *Packard*).

That is, “claims are required to be cast in clear—as opposed to ambiguous, vague, indefinite—terms.” *Packard*, 751 F.3d at 1313.

In the present case, we agree with the Examiner that Appellant’s claims do not inform skilled artisans about the scope of the claimed invention with reasonable certainty. In particular, we agree with the Examiner that it is not clear what specific amounts of stabilized chlorine dioxide are encompassed by the recitation “stabilized chlorine dioxide that remains stable in the composition” as recited in Appellant’s claim 44.

We agree with Appellant that, in “the situation in which a patent applicant has elected to be a lexicographer by providing an explicit definition in the specification for a claim term . . . , the definition selected by the patent applicant controls.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998).

We are not persuaded, however, that the definition of stability provided in Appellant’s Specification informs skilled artisans about the scope of the claimed invention with reasonable certainty.

Appellant’s Specification states as follows: “*Stability* is defined for the purposes of the present invention as the ability to maintain levels of the fluoride ion source, chlorine dioxide source, and pH within the levels specified by the present invention when the final composition is placed under normal storage conditions and accelerated conditions (described above).” Spec. 34. However, we find that there are no “levels specified by the present invention.”

As to the normal storage conditions and accelerated storage conditions specified in the definition of “stability,” Appellant’s Specification states as follows:

- 1) Normal storage conditions of approximately 25 degrees Celsius (C) and 60% Relative Humidity for a storage period of one (1) year, preferably two (2) years, but most preferred for three (3) years, or
- 2) Accelerated conditions of approximately 40 degrees C and 75% Relative Humidity for a storage period of three (3) months, but preferably six (6) months

Spec. 34.

Thus, as seen above, the storage conditions do not identify levels of chloride dioxide source that are maintained nor does the definition of stability. The portions of the Specification identified by Appellant as allegedly providing clarity simply require the source chlorine dioxide levels to be maintained “within the levels specified by the present invention” when the final composition is placed in either the normal storage conditions or the accelerated storage conditions described in the Specification. Spec. 34.

However, Appellant does not explain which particular chlorine dioxide levels are “specified by the present invention.” *See* Appeal Br. 6–7 (citing definition on page 34 of Specification but not identifying any particular chlorine dioxide levels as being “specified by the present invention”); *see also* Reply Br. 6–7 (same). Nor does Appellant identify where those particular levels may be found in the Specification. *See id.* Although Appellant argues that the definition and storage description establishes that the phrase at issue “means that the stabilized chlorine dioxide ingredient of the composition remains *within the claimed levels* during storage and is available to release chlorine dioxide gas when used by a consumer, i.e., when introduced into the oral cavity,” Appeal Br. 7 (emphasis added), the claims do not indicate ranges that meet the definition, nor does the Specification definition.

Although not cited in Appellant's arguments, the Specification's Table 5 shows a 90 day accelerated stability test in which Stabilized Chlorine Dioxide is in the composition at a starting concentration of 0.125% (w/w) and after 90 days the Stabilized Chlorine Dioxide concentration is reduced to 0.04%. *See* Spec. 35. The Specification relies on this stability study in concluding that the definition of stability "is achievable." Spec. 35. However, the example does not identify "levels specified by the present invention."

Elsewhere, although again not cited in Appellant's arguments, the Specification provides that, "[f]or the present invention, the instructed levels *of the chlorine dioxide source* in the oral care compositions are 0.005% to 0.800% weight/weight (w/w) or weight/volume (w/v) stabilized chlorine dioxide." Spec. 17 (emphasis added).

We do not find the foregoing establishes clarity regarding the claim requirement of "stabilized chlorine dioxide that remains stable in the composition." The Specification defines stability in terms of "levels" of chlorine dioxide source maintained "within the levels specified by the present invention" when placed under certain storage conditions. The Specification, however, provides multiple different concentration levels of stabilized chlorine dioxide (and its source) which are described as being "within the levels specified by the present invention." It is therefore unclear how much stabilized chlorine dioxide must remain in the composition after being stored under the specified conditions, in order to be stable according to the definition of stability provided in Appellant's Specification. Accordingly, we find that the definition of stability provided by Appellant's Specification is ambiguous, and therefore fails to inform a skilled artisan

about the scope of Appellant's invention with reasonable certainty. We therefore agree with the Examiner that claim 44's recitation of "stabilized chlorine dioxide that remains stable in the composition" renders claim 44, and its dependent claims, indefinite.

In sum, for the reasons discussed, Appellant does not persuade us that the Examiner erred in determining that claim 44, and its dependent claims 45, 46, and 49–60 are ambiguous, and therefore fail to inform a skilled artisan about the scope of Appellant's invention with reasonable certainty. Accordingly, we affirm the Examiner's rejection of claims 44–46 and 49–60 for indefiniteness.

OBVIOUSNESS

In rejecting claims 44–46 and 49–60 for obviousness, the Examiner determined that a skilled artisan would have had motivation and a reasonable expectation of success in including sodium fluoride in the stabilized chlorine dioxide-containing compositions of Christopfel, based on the teachings in Oxyfresh C and Jensen. Ans. 7.

Appellant contends that, because the xylitol in the compositions of Christopfel, Oxyfresh C, and Jensen degrades stabilized chlorine dioxide, Christopfel, Oxyfresh C, and Jensen therefore do not describe or suggest compositions that meet claim 44's requirement for the claimed composition to contain "stabilized chlorine dioxide that remains stable in the composition." *See* Appeal Br. 9–11 (citing Grootveld Declaration);⁷ Reply Br. 9.

⁷ Declaration of Martin Grootveld, Ph.D., signed Nov. 12, 2018.

As discussed above, we agree with the Examiner that independent claim 44's recitation of "stabilized chlorine dioxide that remains stable in the composition" renders claim 44, and its dependent claims, indefinite. In particular, as discussed above, it is unclear on the current record how much stabilized chlorine dioxide must remain in the claimed composition when stored under the conditions described in the Specification, in order for the chlorine dioxide to "remain[] stable in the composition" as required by claim 44. We find, therefore, that the scope of the claimed subject matter is so uncertain that we cannot meaningfully perform the required comparison between the composition recited in claim 44, and the compositions of the cited prior art. *See In re Steele*, 305 F.2d 859, 863 (CCPA 1962) (obviousness rejection of indefinite claim reversed where claim interpretation required resort to "unsupported speculative assumptions" as to scope of claimed subject matter).

Because review of the merits of the appealed obviousness rejection of claims 44–46 and 49–60 would require resort to unsupported speculative assumptions as to the scope of the claimed subject matter, we reverse the Examiner's obviousness rejection of claims 44–46 and 49–60 *pro forma*. *See Ex parte Miyazaki*, 89 USPQ2d at 1217 (precedential) (reversing rejections *pro forma* under *In re Steele* when consideration of merits of rejections requires "speculative assumption as to the meaning of the claims").

DECISION SUMMARY

In summary:

Claim(s) Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
44–46, 49–60	112	Indefiniteness	44–46, 49–60	
44–46, 49–60	103	Christopfel, Oxyfresh C, Jensen, Hill		44–46, 49–60
Overall Outcome			44–46, 49–60	

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