

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 28

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JED E. ROSE
and FREDERIQUE M. BEHM

Appeal No. 96-3923
Application 08/309,790¹

ON BRIEF

Before MEISTER, STAAB and CRAWFORD, Administrative Patent Judges.

MEISTER, Administrative Patent Judge.

DECISION ON APPEAL

Jed E. Rose and Frederique M. Behm (the appellants)
appeal from the final rejection of claims 1-28, the only

¹ Application for patent filed September 21, 1994. According to appellants, the application is a continuation-in-part of Application 07/979,804, filed November 20, 1992, now abandoned.

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claims present in the application.

We AFFIRM-IN-PART.

The appellants' invention pertains to a method and device for reducing the incidence of tobacco smoking wherein an irritant is utilized to simulate respiratory tract sensations in a user that are substantively similar to those obtained by inhalation of tobacco smoke. Independent claims 1 and 8 are further illustrative of the appealed subject matter and copies thereof may be found in the appendix to the appellants' brief.

The references relied on by the examiner are:

Rose	4,715,387	Dec. 29,
1987		
Ray et al. (Ray)	4,800,903	Jan. 31, 1989

Fuller et al. (Fuller), American Physiological Society,
?Bronchoconstrictor response to inhaled capsaicin in humans?,
pages 1080-1084 (1985).

Claims 15-28 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to (1) provide an adequate written description of the invention, (2) adequately teach how to make and use the invention and (3) present a best mode of carrying out the invention.

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Claims 15-28 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which the appellants regard as the invention.

Claims 1, 5-8 and 12-14 stand rejected under 35 U.S.C. § 103 as being unpatentable over Fuller in view of Rose.

Claims 1-4 and 8-11 stand rejected under 35 U.S.C. § 103 as being unpatentable over Fuller in view of Ray.

The examiner's rejections are explained on pages 3-6 of the answer.² The arguments of the appellants in support of their position are found on pages 8-19 of the brief and pages 1-4 of the reply brief.

OPINION

At the outset, we note the appellants on page 7 of the brief state that:

1. method claims 1-7 stand or fall together as a first group;
2. device claims 8-14 stand or fall together as a

² The answer contains no "Response to Argument" as expressly required by **Manual of Patent Examining Procedure** (MPEP) § 1208 (6th ed., Rev. 3, Jul. 1997).

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second group;

3. method claims 15 and 17-22 stand or fall together
as a third group; and

4. device claims 16 and 23-28 stand or fall together
as a fourth group.

Accordingly, group 1 will stand or fall with representative
claim 1; group 2 will stand or fall with representative claim
8; group 3 will stand or fall with representative claim 15;
and group 4

will stand or fall with representative claim 16. See 37 CFR
§ 1.192(c)(7).

We have carefully reviewed the appellants' invention as
described in the specification, the appealed claims, the
examiner's statement of the rejections, the prior art applied
by the examiner and the arguments advanced by the appellants
in the brief and reply brief. As a consequence of this
review, we will reverse the rejections of claims 15-28 under
35 U.S.C. § 112, first and second paragraphs and, with respect
to the rejections under 35 U.S.C. § 103, we will (1) reverse
the rejection of claims 1 and 5-7 based on the combined

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teachings of Fuller and Rose, (2) affirm the rejection of claims 8 and 12-14 based on the combined teachings of Fuller and Rose, (3) reverse the rejection of claims 1-4 based on the combined teachings of Fuller and Ray and (4) affirm the rejection of claims 8-11 based on the combined teachings of Fuller and Ray.

Considering first the rejection of claims 15-28 under 35 U.S.C. § 112, first paragraph, the examiner's rejection appears to be based on the enablement requirement of that provision.³

More specifically, the examiner is of the opinion that the "whereby" clauses of claims 15 and 16 are

inadequately and insufficiently described and taught. There is no factual disclosure to determine when the respiratory tract sensations created by the irritant are sufficient to simulate those created by tobacco smoke to reduce the need of the user to smoke tobacco, yet insufficient to

³ The description requirement found in the first paragraph of § 112 is separate from the enablement requirement of that provision. *See Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560-64, 19 USPQ2d 1111, 1114-17 (Fed. Cir. 1991) and *In re Barker*, 559 F.2d 588, 591, 194 USPQ 470, 472 (CCPA 1977), *cert. denied, sub. nom, Barker v. Parker*, 434 U.S. 1064 (1978).

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create a gross bronchoconstrictor response in the user. The quantity, strength or the like of the irritant needed to achieve the desired results of sufficiently simulating respiratory tract smoking sensations while not creating gross bronchoconstrictor response is not disclosed. No comparative test results have been submitted. [Answer, page 5.]

Considering first the rejection under 35 U.S.C. § 112, first paragraph, we note that the test regarding enablement is whether the disclosure, as filed, is sufficiently complete to enable one of ordinary skill in the art to make and use the claimed invention without undue experimentation. **See In re Scarbrough**, 500 F.2d 560, 566, 182 USPQ 298, 302 (CCPA 1974) and **In re Wands**, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Additionally, as the court in **In re Gaubert**, 524 F.2d 1222, 1226, 187 USPQ 664, 667 (CCPA 1975) set forth in quoting from **Martin v. Johnson**, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972):

To satisfy §112, the specification disclosure must be sufficiently complete to enable one of ordinary skill in the art to make the invention without undue experimentation, although the need for a

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minimum amount of experimentation is not fatal * * *. Enablement is the criterion, and every detail need not be set forth in the written specification if the skill in the art is such that the disclosure enables one to make the invention. [Citations omitted.]

The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. *See Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. & Int. 1986).

Here, with respect to the irritants utilized in the invention, the appellants' specification on pages 9 and 10 teaches that (1) oleoresins of black and/or red pepper are dissolved in a liquid carrier such as ethanol or propylene glycol "at about .01 to .10 weight percent" and (2) nonvolatile constituents such as capsaicin are dissolved in a liquid carrier such as ethanol or propylene glycol "at about .0002 to .005 weight percent" in order to achieve the results stated in the specification. Page 5 of the specification of the parent application stated that the object of the invention was to "simulate the sensation created by tobacco smoke" and a

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preliminary amendment (Paper No. 15) filed concurrently with the instant continuation-in-part application⁴ amended page 5 of the specification to state that the sensations created by the irritant are

sufficient to simulate those created by tobacco smoke to reduce the need of the user to smoke tobacco but insufficient to create a gross bronchoconstrictor response in the user.

Thus, taken as a whole, the appellants' specification contains a teaching that the above-noted amounts of irritant set forth on pages 9 and 10 are sufficient to simulate sensations created by tobacco smoke but insufficient to create a gross bronchoconstrictor response in a user. As the court in *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) stated

a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in

⁴ See *Manual of Patent Examining Procedure* (MPEP) § 608.04(b) (6th ed., Rev. 3, Jul. 1997): "An amendment which adds additional disclosure filed with a request for a continuation-in-part application under 37 CFR 1.62 is automatically considered a part of the original disclosure of the application by virtue of the rule."

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describing and defining the subject matter sought to be patented **must** be taken as in compliance with the enabling requirement of the first paragraph of § 112 **unless** there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

Here, the examiner has not provided any reasonable line of reasoning for doubting the objective truth of the appellants' statements concerning the disclosed amounts of irritant and the results they produce. In this regard, it is well settled that the examiner has the initial burden of producing reasons that substantiate a rejection based on lack of enablement. *See Marzocchi*, 439 F.2d at 224, 169 USPQ at 370 and *In re Strahilevitz*, 668 F.2d 1229, 1232, 212 USPQ 561, 563 (CCPA 1982). The examiner, however, has failed to satisfy this burden. Accordingly, we will not sustain the rejection of claims 15-28 under 35 U.S.C. § 112, first paragraph.

Turning to the rejection of claims 15-28 under 35 U.S.C. § 112, second paragraph, the examiner is of the opinion that these claims are indefinite because "no quantity, strength or the like of irritant is recited" (answer, page 6). We do not agree with the examiner's position. The legal standard for

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indefiniteness is whether a claim reasonably apprises those of skill in the art of its scope. ***In re Warmerdam***, 33 F.3d 1354, 1361, 31 USPQ2d 1754, 1759 (Fed. Cir. 1994). Here, the examiner has not even alleged that one of ordinary skill in this art would not be reasonably be apprised of the scope of these claims. Instead, the examiner's position is bottomed on the fact that no particular amount or quantity of irritant has been set forth. Such a criticism, however, goes to the breadth of the claim and it is well settled that breadth alone is not to be equated with indefiniteness. ***See In re Johnson***, 558 F.2d 1008, 1016 n.17, 194 USPQ 187, 194 n.17 (CCPA 1977); ***In re Miller***, 441 F.2d 689, 693, 169 USPQ 597, 600 (CCPA 1971); ***In re Gardner***, 427 F.2d 786, 788, 166 USPQ 138, 140 (CCPA 1970) and ***Ex parte Scherberich***, 201 USPQ 397, 398 (Bd. App. 1977). Even though a specific amount or quantity of irritant has not been set forth, we see no reason why one of ordinary skill in this art would not be reasonably apprised of the scope of claims 15-28. This being the case, we will not sustain the rejection of claims 15-28 under 35 U.S.C. § 112, second paragraph.

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Considering next the rejections under 35 U.S.C. § 103 of claims 1 and 5-7 based on the combined teachings of Fuller and Rose and claims 1-4 based on the combined teachings of Fuller and Ray, each of these claims is directed to a **method** for reducing the incidence of tobacco by simulating respiratory tract sensations in a user substantively similar to those obtained by inhalation of tobacco smoke. The answer states that:

Fuller describes an experiment wherein capsaicin, an extract, or constituent, of pepper, was inhaled by human subjects (see page 1080, column 1, first (abstract) paragraph and column 2, paragraph beginning "Drug Delivery" in particular). The device used was a nebulizer. This is the same method as here claimed. [Page 3.]

Thereafter, the examiner concludes that it would have been obvious (1) "to have used the aerosol device of Rose in order to deliver the capsaicin to the human subjects" (answer, page 4) and (2) "to have used the tube of Ray as the nebulizer in the method of Fuller, substituting capsaicin for nicotine, in order to deliver the capsaicin to human subjects" (answer, page 4).

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We cannot agree with the examiner's assertion that the "method" of Fuller is the "same" as that being claimed in independent claim 1. Independent claim 1 sets forth:

A method ***for reducing the incidence of tobacco smoking*** by simulating respiratory tract sensations . . . whereby the respiratory tract sensations created by said irritant simulate those created by tobacco smoke ***to reduce the need of the user to smoke tobacco***. [Emphasis ours.]

It is thus clear that the method set forth in independent claim 1 is directed to the process of using an irritant such as capsaicin to reduce the smoking of tobacco by a user. While both Fuller's method and the method defined by independent claim 1 include the steps of repeatedly inhaling an irritant such as capsaicin, Fuller neither teaches nor suggests the use of this irritant to reduce the need of a user to smoke tobacco. Instead, Fuller's method is directed to the measurement of bronchoconstrictor response in humans after an irritant such as capsaicin has inhaled by a user. Inasmuch as 35 U.S.C. § 100(b) expressly recognizes "a new use of a known process," the particular use to which the process is directed

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cannot be ignored as the examiner apparently has done. **See, e.g., In re Zierden**, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969).

The examiner has merely relied on Rose for the teaching of an aerosol device and on Ray for the teaching of a dispenser (which dispenses nicotine). In any event, we have carefully reviewed the teachings of Rose and Ray and find nothing in the combined disclosures of Fuller and either Rose or Ray which would fairly suggest the method set forth in independent claim 1. Therefore, we will not sustain the rejections under 35 U.S.C.

§ 103 of claims 1 and 5-7 based on the combined teachings of Fuller and Rose and claims 1-4 based on the combined teachings of Fuller and Ray.

Considering last the rejections under 35 U.S.C. § 103 of claims 8 and 12-14 as being unpatentable over Fuller in view of Rose and claims 8-11 as being unpatentable over Fuller in view of Ray, we initially note that each of these claims is directed to a **device** for reducing the incidence of tobacco by simulating respiratory tract sensations in a user

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substantively similar to those obtained by inhalation of tobacco smoke. Fuller provides a nebulizer (see the last full paragraph on page 1080) which contains capsaicin (see, e.g., the penultimate paragraph on page 1080) and is "adapted" to be introduced into a user's mouth for inhalation. While the examiner has additionally relied on the teachings of either Rose or Ray for the particular type of inhalation device, the nebulizer of Fuller satisfies the limitations of the inhalation device as broadly set forth in representative claim 8 and, accordingly, we see no need to resort to the teachings of either Rose or Ray insofar as the limitations of representative claim 8 are concerned.

The appellants argue that there is no suggestion in Fuller to use the inhalation device or nebulizer for the purpose of having smokers inhale capsaicin so as to reduce their incidence of smoking tobacco. This is true. We must point out, however, the particular manner in which a device or article is used cannot be relied on to distinguish structure from the prior art. *See, e.g., In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997), *In re*

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Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990), **In re Yanush**, 477 F.2d 958, 959, 177 USPQ 705, 706 (CCPA 1973) and **In re Casey**, 370 F.2d 576, 580, 152 USPQ 235, 238 (CCPA 1967). Here, the device of Fuller (i.e., nebulizer) clearly has the **capability** of being used in the claimed manner and whether Fuller's device actually is or might be used to reduce the need of a user to smoke tobacco depends upon the performance or nonperformance of a future act of use rather than a structural distinction in the claims. Stated differently, the nebulizer of Fuller would not undergo a metamorphosis to a new device simply because it was used to reduce the need of a user to smoke tobacco. **See In re Pearson**, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) and **Ex parte Masham**, 2 USPQ2d 1647, 1648 (Bd. Pat. App. & Int. 1987).

In view of the foregoing, we will sustain the rejections under 35 U.S.C. § 103 of claims 8 and 12-14 as being

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unpatentable over Fuller in view of Rose and claims 8-11 as being unpatentable over Fuller in view of Ray.

In summary:

The rejections of claims 15-28 under 35 U.S.C. § 112, first and second paragraphs, are reversed.

The rejections under 35 U.S.C. § 103 of claims 1 and 5-7 as being unpatentable over Fuller in view of Rose and claims 1-4 as being unpatentable over Fuller in view of Ray are reversed.

The rejections under 35 U.S.C. § 103 of claims 8 and 12-14 as being unpatentable over Fuller in view of Rose and claims 8-11 as being unpatentable over Fuller in view of Ray are affirmed.

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

AFFIRMED-IN-PART

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JAMES M. MEISTER)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
LAWRENCE J. STAAB)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
)	
MURRIEL E. CRAWFORD))
Administrative Patent Judge)	

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Richard J. Jenkins
University Tower, Ste. 1600
3100 Tower Road
Durham, NC 27707