

Exhibit 18

Manual of PATENT EXAMINING PROCEDURE

Original Eighth Edition, August 2001

Latest Revision August 2006



U.S. DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

The U.S. Patent and Trademark Office does not handle the sale of the Manual, distribution of notices and revisions, or change of address of those on the subscription list. Correspondence relating to existing subscriptions should be sent to the Superintendent of Documents at the following address:

Superintendent of Documents Telephone: 202-512-2267
Mail List Section
Washington, DC 20402

Inquiries relating to purchasing the Manual should be directed to:

Superintendent of Documents Telephone: 202-512-1800
United States Government Printing Office
Washington, DC 20402

Orders for reproduced copies of individual replacement pages or of previous revisions of the Manual should be sent to the following address:

Mail Stop Document Services Telephone: 1-800-972-6382 or 571-272-3150
Director of the U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Previous editions and revisions of the Manual are available on microfilm in the Patent Search Room.
The Manual is available on CD-ROM and on diskette from:

U.S. Patent and Trademark Office Telephone: 571-272-5600
Office of Electronic Information Products
MDW 4C18, P.O. Box 1450
Alexandria, VA 22313-1450

Employees of the U.S. Patent and Trademark Office should direct their requests for the Manual, replacement pages, notices, and revisions to the Office of Patent Training. Telephone: 571-272-7222

Pursuant to the Patent and Trademark Office Efficiency Act (PTOEA) (Pub. L. 106-113, 113 Stat. 1501A-572), the head of the United States Patent and Trademark Office (USPTO) is the "Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office." The Director is assisted by the "Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office." The patent operations of the USPTO are now headed by the "Commissioner for Patents." The trademark operations of the USPTO are now headed by the "Commissioner for Trademarks." Under section 4741(b) of the PTOEA, any reference to the Commissioner of Patents and Trademarks, the Assistant Commissioner for Patents, or the Assistant Commissioner for Trademarks is deemed to refer to the Director, the Commissioner for Patents, or the Commissioner for Trademarks, respectively. See "Reestablishment of the Patent and Trademark Office as the United States Patent and Trademark Office" published in the *Federal Register* at 65 FR 17858 (Apr. 5, 2000), and in the *Official Gazette of the United States Patent and Trademark Office* at 1234 O.G. 41 (May 9, 2000).

Additions to the text of the Manual are indicated by arrows (><) inserted in the text. Deletions are indicated by a single asterisk (*) where a single word was deleted and by two asterisks (**) where more than one word was deleted. The use of three or five asterisks in the body of the laws, rules, treaties, and administrative instructions indicates a portion of the law, rule, treaty, or administrative instruction which was not reproduced.

First Edition, November 1949
Second Edition, November 1953
Third Edition, November 1961
Fourth Edition, June 1979
Fifth Edition, August 1983
Sixth Edition, January 1995
Seventh Edition, July 1998
Eighth Edition, August 2001
Revision 1, February 2003
Revision 2, May 2004
Revision 3, August 2005
Revision 4, October 2005
Revision 5, August 2006

2173.05(d)

MANUAL OF PATENT EXAMINING PROCEDURE

In re Fredericksen 213 F.2d 547, 102 USPQ 35 (CCPA 1954). The more recent cases have tended to accept a limitation such as “an effective amount” as being definite when read in light of the supporting disclosure and in the absence of any prior art which would give rise to uncertainty about the scope of the claim. In *Ex parte Skuballa*, 12 USPQ2d 1570 (Bd. Pat. App. & Inter. 1989), the Board held that a pharmaceutical composition claim which recited an “effective amount of a compound of claim 1” without stating the function to be achieved was definite, particularly when read in light of the supporting disclosure which provided guidelines as to the intended utilities and how the uses could be effected.

2173.05(d) Exemplary Claim Language (“for example,” “such as”) [R-1]

Description of examples or preferences is properly set forth in the specification rather than the claims. If stated in the claims, examples and preferences may lead to confusion over the intended scope of a claim. In those instances where it is not clear whether the claimed narrower range is a limitation, a rejection under 35 U.S.C. 112, second paragraph should be made. The examiner should analyze whether the metes and bounds of the claim are clearly set forth. Examples of claim language which have been held to be indefinite because the intended scope of the claim was unclear are:

(A) “R is halogen, for example, chlorine”;

(B) “material such as rock wool or asbestos” *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1949);

(C) “lighter hydrocarbons, such, for example, as the vapors or gas produced” *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949); and

(D) “normal operating conditions such as while in the container of a proportioner” *Ex parte Steigerwald*, 131 USPQ 74 (Bd. App. 1961).

>The above examples of claim language which have been held to be indefinite are fact specific and should not be applied as *per se* rules. See MPEP § 2173.02 for guidance regarding when it is appropriate to make a rejection under 35 U.S.C. 112, second paragraph.<

2173.05(e) Lack of Antecedent Basis [R-5]

A claim is indefinite when it contains words or phrases whose meaning is unclear. The lack of clarity could arise where a claim refers to “said lever” or “the lever,” where the claim contains no earlier recitation or limitation of a lever and where it would be unclear as to what element the limitation was making reference. Similarly, if two different levers are recited earlier in the claim, the recitation of “said lever” in the same or subsequent claim would be unclear where it is uncertain which of the two levers was intended. A claim which refers to “said aluminum lever,” but recites only “a lever” earlier in the claim, is indefinite because it is uncertain as to the lever to which reference is made. Obviously, however, the failure to provide explicit antecedent basis for terms does not always render a claim indefinite. If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite. >*Energizer Holdings Inc. v. Int’l Trade Comm’n*, 435 F.3d 1366, 77 USPQ2d 1625 (Fed. Cir. 2006) (holding that “anode gel” provided by implication the antecedent basis for “zinc anode”); < *Ex parte Porter*, 25 USPQ2d 1144, 1145 (Bd. Pat. App. & Inter. 1992) (“controlled stream of fluid” provided reasonable antecedent basis for “the controlled fluid”). Inherent components of elements recited have antecedent basis in the recitation of the components themselves. For example, the limitation “the outer surface of said sphere” would not require an antecedent recitation that the sphere has an outer surface. See *Bose Corp. v. JBL, Inc.*, 274 F.3d 1354, 1359, 61 USPQ2d 1216, 1218-19 (Fed. Cir. 2001) (holding that recitation of “an ellipse” provided antecedent basis for “an ellipse having a major diameter” because “[t]here can be no dispute that mathematically an inherent characteristic of an ellipse is a major diameter”).

EXAMINER SHOULD SUGGEST CORRECTIONS TO ANTECEDENT PROBLEMS

Antecedent problems in the claims are typically drafting oversights that are easily corrected once they are brought to the attention of applicant. The examiner’s task of making sure the claim language complies with the requirements of the statute should be carried out in a positive and constructive way, so that minor problems can be identified and easily

corrected, and so that the major effort is expended on more substantive issues. However, even though indefiniteness in claim language is of semantic origin, it is not rendered unobjectionable simply because it could have been corrected. *In re Hammack*, 427 F.2d 1384 n.5, 166 USPQ 209 n.5 (CCPA 1970).

A CLAIM TERM WHICH HAS NO ANTECEDENT BASIS IN THE DISCLOSURE IS NOT NECESSARILY INDEFINITE

The mere fact that a term or phrase used in the claim has no antecedent basis in the specification disclosure does not mean, necessarily, that the term or phrase is indefinite. There is no requirement that the words in the claim must match those used in the specification disclosure. Applicants are given a great deal of latitude in how they choose to define their invention so long as the terms and phrases used define the invention with a reasonable degree of clarity and precision.

A CLAIM IS NOT *PER SE* INDEFINITE IF THE BODY OF THE CLAIM RECITES ADDITIONAL ELEMENTS WHICH DO NOT APPEAR IN THE PREAMBLE

The mere fact that the body of a claim recites additional elements which do not appear in the claim's preamble does not render the claim indefinite under 35 U.S.C. 112, second paragraph. See *In re Larsen*, No. 01-1092 (Fed. Cir. May 9, 2001) (unpublished) (The preamble of the *Larsen* claim recited only a hanger and a loop but the body of the claim positively recited a linear member. The examiner rejected the claim under 35 U.S.C. 112, second paragraph, because the omission from the claim's preamble of a critical element (i.e., a linear member) renders that claim indefinite. The court reversed the examiner's rejection and stated that the totality of all the limitations of the claim and their interaction with each other must be considered to ascertain the inventor's contribution to the art. Upon review of the claim in its entirety, the court concluded that the claim at issue apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, paragraph 2.).

2173.05(f) Reference to Limitations in Another Claim

A claim which makes reference to a preceding claim to define a limitation is an acceptable claim construction which should not necessarily be rejected as improper or confusing under 35 U.S.C. 112, second paragraph. For example, claims which read: "The product produced by the method of claim 1." or "A method of producing ethanol comprising contacting amylose with the culture of claim 1 under the following conditions" are not indefinite under 35 U.S.C. 112, second paragraph, merely because of the reference to another claim. See also *Ex parte Porter*, 25 USPQ2d 1144 (Bd. Pat. App. & Inter. 1992) where reference to "the nozzle of claim 7" in a method claim was held to comply with 35 U.S.C. 112, second paragraph. However, where the format of making reference to limitations recited in another claim results in confusion, then a rejection would be proper under 35 U.S.C. 112, second paragraph.

2173.05(g) Functional Limitations [R-3]

A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper. *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step. >*In Innova/Pure Water Inc. v. Safari Water Filtration Sys. Inc.*, 381 F.3d 1111, 1117-20, 72 USPQ2d 1001, 1006-08 (Fed. Cir. 2004), the court noted that the claim term "operatively connected" is "a general descriptive claim term frequently used in patent drafting to reflect a functional relationship between claimed components," that is, the term "means the claimed components must be connected in a way to perform a designated function." "In the absence of modifiers,