reduction to practice has occurred, as well as a method for obtaining it, so as to distinguish it from other materials, envision the detailed constitution of a gene. We hold that when an inventor is unable to any material with that biological property. conception having no more specificity than physical or chemical properties, or whatever define it by its method of preparation, its characteristics sufficiently distinguish it. It is describe how to obtain it. conception does that the inventor be able to conception of a chemical compound requires one, and it is well established in our law that USPQ2d 1016, 1021 (Fed. Cir. 1991)(``A gene reads). that the PTO has the initial encoding

See, e.g., In re Robertson, 169 F.3d at 743, 745, 49 USPQ2d at 1949, 1950—51 (Fed. Cir. 1999)(``To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’ '') (citations omitted). 57. When an explicit limitation in a claim ‘is not present in the written description whose benefit is sought must be shown that a person of ordinary skill would have understood, at the time the patent was filed, that the description requires that limitation.’ Hyatt v. Boone, 146 F.3d 1348, 1353, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998). 58. See, e.g., Johnson Worldwide Associates Inc. v. Zebo Corp., 175 F.3d at 993, 50 USPQ2d at 1613; Gentry Galleys, Inc. v. Berkline Corp., 134 F.3d at 1479, 45 USPQ2d at 1503; Tronzo v. Biotem, Inc., 156 F.3d at 1159, 47 USPQ2d at 1833; and Reiffin v. Microsoft Corp., 48 USPQ2d at 1277. 59. See, e.g., In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). 60. Wertheim, 541 F.2d at 262, 191 USPQ at 96. 61. See In re Rasmussen, 650 F.2d at 1214, 211 USPQ at 326. 62. See In re Alton, 76 F.3d 1168, 1176, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996). Dated: December 16, 1999. Q. Todd Dickinson, Assistant Secretaries of Commerce and Commissioner of Patents and Trademarks. [FR Doc. 99—33053 Filed 12—20—99; 8:45 am] BILLING CODE 3510—15—P DEPARTMENT OF COMMERCE Patent and Trademark Office [Docket No. 991027289—9289—01] RIN 0651—AB09 Revised Utility Examination Guidelines; Request for Comments AGENCY: Patent and Trademark Office, Commerce. ACTION: Notice and request for public comments.

SUMMARY: The Patent and Trademark Office (PTO) requests comments from any interested member of the public on the following Revised Utility Examination Guidelines. The PTO is publishing a revised version of guidelines to be used by Office personnel in their review of patent applications for compliance with the utility requirement based on comments received in response to the Request for Comments on Interim Guidelines for Examination of Patent Applications. Under the 35 U.S.C. 112, ¶ 1 “Written Description” Requirement; Extension of Comment Period and Notice of Hearing, 63 FR 50887 (September 23, 1998). These Revised Utility Guidelines will be used by PTO personnel in their review of patent applications for compliance with the “utility” requirement of 35 U.S.C. 101. This revision supersedes the Utility Examination Guidelines that were published at 60 FR 36263 (1995) and at 1177 O.G. 146 (1995).

DATES: Written comments on the Revised Utility Examination Guidelines will be accepted by the PTO until March 22, 2000.

ADDRESSES: Written comments should be addressed to Box 8, Commissioner of Patents and Trademarks, Washington, DC 20231, marked to the attention of Mark Nagumo, or to Box Comments, Assistant Commissioner for Patents, Washington, DC 20231, marked to the attention of Linda S. Therkorn. Alternatively, comments may be submitted to Mark Nagumo via facsimile at (703) 305—9373 or by electronic mail addressed to “mark.nagumo@uspto.gov”; or to Linda Therkorn via facsimile at (703) 305—8825 or by electronic mail addressed to “linda.therkorn@uspto.gov”.

FOR FURTHER INFORMATION CONTACT: Mark Nagumo by telephone at (703) 305—8666, by facsimile at (703) 305—9373, by electronic mail “mark.nagumo@uspto.gov,” or by mail marked to his attention addressed to the Commissioner of Patents and Trademarks, Box 8, Washington, DC 20231; or Linda Therkorn by telephone at (703) 305—9323, by facsimile at (703) 305—8825, by electronic mail “linda.therkorn@uspto.gov,” or by mail marked to her attention addressed to Box Comments, Assistant Commissioner of Patents and Trademarks, Washington, DC 20231.

SUPPLEMENTARY INFORMATION: The PTO requests comments from any interested member of the public on the following Revised Utility Examination Guidelines. As of the publication date of this notice, this revision will be used by PTO personnel in their review of patent
applications for compliance with the "utility" requirement of 35 U.S.C. 101. Because this revision governs internal practices, it is exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A).

Written comments should include the following information: (1) Name and affiliation of the individual responding, and (2) an indication of whether the comments offered represent views of the respondent's organization or are respondent's personal views.

Parties presenting written comments are requested, where possible, to provide their comments in machine-readable format in addition to a paper copy. Such submissions may be provided by electronic mail messages sent over the Internet, or on a 3.5" floppy disk formatted for use in a Macintosh, Windows, Windows for Workgroups, Windows 95, Windows 98, Windows NT, or MS-DOS based computer.

Written comments will be available for public inspection on or about April 19, 2000, in Suite 918, Crystal Park 2, 2121 Crystal Drive, Arlington, Virginia. In addition, comments provided in machine readable format will be available through the PTO's Website at http://www.uspto.gov.

I. Discussion of Public Comments

Comments received by the Office in response to the request for public comment on the Interim Written Description Guidelines regarding the patentability of expressed sequence tags (ESTs) suggested the need for revision or clarification of the final Utility Examination Guidelines as published at 60 FR 36263 (1995) and 1177 O.G. 146 (1995). All comments have been carefully considered. Many comments stated that sufficient patentable utility has not been shown when the sole disclosed use of an EST is to identify other nucleic acids whose utility was not known, and the function of the corresponding gene is not known. Moreover, several comments opined that ESTs are genomic research tools that should be available for unencumbered research to advance the public good. One comment stated that asserted utilities for ESTs, such as mapping the genome or tissue typing, would probably not satisfy the requirements of 35 U.S.C. 101 if the length of the attached DNA sequence were greatly extended. Other comments stated that the disclosure of a DNA sequence alone is insufficient to enable scientists to use ESTs for mapping or tissue typing. Some comments suggested that PTO examination procedures would result in granting patents based on nonspecific and nonsubstantial utilities, contrary to established case law. See Brenner v. Manson, 383 U.S. 519, 534–35, 148 USPQ 689, 695 (1966) (requiring disclosure of "specific utility," and of "substantial utility," "where specific benefit exists in currently available form"); accord, In re Ziegler, 992 F.2d 1197, 1201, 26 USPQ2d 1600, 1603 (Fed. Cir. 1996) (requiring that a specific and substantial or practical utility for the invention be disclosed as a condition of meeting the practical utility requirement of § 101). Consequently, a number of changes have been made to the Utility Examination Guidelines to clarify the requirements of 35 U.S.C. 101 and 112, (Fed. Cir. 1996) (requiring that a specific and substantial or practical utility for the invention be disclosed as a condition of meeting the practical utility requirement of § 101).

II. Guidelines for Examination of Applications for Compliance With the Utility Requirement

A. Introduction

The following guidelines establish the policies and procedures to be followed by Office personnel in the evaluation of any patent application for compliance with the utility requirements of 35 U.S.C. 101 and 112. These guidelines have been promulgated to assist Office personnel in their review of applications for compliance with the utility requirement. The guidelines do not alter the substantive requirements of 35 U.S.C. 101 and 112, nor are they designed to obviate the examiner's review of applications for compliance with all other statutory requirements for patentability.

B. Examination Guidelines for the Utility Requirement

Office personnel are to adhere to the following procedures when reviewing patent applications for compliance with the "useful invention" ("utility") requirement of 35 U.S.C. 101 and 112, first paragraph.

1. Read the claims and the supporting written description.
   (a) Determine what the applicant has claimed, noting any specific embodiments of the invention.
   (b) Ensure that the claims define statutory subject matter (i.e., a process, machine, manufacture, composition of matter, or improvement thereof).

2. Review the claims and the supporting written description to determine if the applicant has asserted for the claimed invention any specific and substantial utility that is credible.
   (a) If the invention has a well-established utility, regardless of any assertion made by the applicant, do not impose a rejection based on lack of utility. An invention has a well-established utility if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process).
   (b) If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility.

1. A claimed invention must have a specific and substantial utility. This requirement excludes "throw-away," "insubstantial," or "nonspecific" utilities, such as the use of a complex invention as landfill, as a way of satisfying the utility requirement of 35 U.S.C. 101.

2. Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions. An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement.

C. If no assertion of specific and substantial utility for the claimed invention made by the applicant is credible, and the claimed invention does not have a well-established utility, reject the claim(s) under section 101 on the grounds that the invention as claimed lacks utility. Also reject the claims under § 112, first paragraph, on the basis that the disclosure fails to teach how to use the invention as claimed. The section 112, first paragraph, rejection imposed in conjunction with a section 101 rejection should incorporate by reference the grounds of the corresponding section 101 rejection.

D. If the applicant has not asserted any specific and substantial utility for the claimed invention and it does not have a well-established utility, impose a rejection under section 101, emphasizing that the applicant has not disclosed a specific and substantial utility for the invention. Also impose a separate rejection under section 112, first paragraph, on the basis that the applicant has not disclosed how to use the invention due to the lack of a specific and substantial utility. The sections 101 and 112 rejections shift the
 burden of coming forward with evidence to the applicant to:
(1) Explicitly identify a specific and substantial utility for the claimed invention; and
(2) Provide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well established at the time of filing. The examiner should review any subsequently submitted evidence of utility using the criteria outlined above. The examiner should also ensure that there is an adequate nexus between the showing and the application as filed.

3. Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility. Whenever possible, the examiner should provide documentary evidence (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) to support the factual basis for the prima facie showing of no specific and substantial credible utility. If documentary evidence is not available, the examiner should specifically explain the scientific basis for his or her factual conclusions.

(a) Where the asserted specific and substantial utility is not credible, a prima facie showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention.

The prima facie showing must contain the following elements:
(1) An explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible;
(2) Support for factual findings relied upon in reaching this conclusion; and
(3) An evaluation of all relevant evidence of record.

(b) Where no specific and substantial utility is disclosed or known, a prima facie showing of no specific and substantial utility must establish that it is more likely than not that a person skilled in the art would not be aware of any well-established credible utility that is both specific and substantial.

The prima facie showing must contain the following elements:
(1) An explanation that clearly sets forth the reasoning used in concluding that there is no known well established utility for the claimed invention that is both specific and substantial;
(2) Support for factual findings relied upon in reaching this conclusion; and
(3) An evaluation of all relevant evidence of record.

4. A rejection based on lack of utility should not be maintained if an asserted utility for the claimed invention would be considered specific, substantial, and credible by a person of ordinary skill in the art in view of all evidence of record.

Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. Similarly, Office personnel must accept an opinion from a qualified expert that is based upon relevant facts whose accuracy is not being questioned; it is improper to disregard the opinion solely because of a disagreement over the significance or meaning of the facts offered.

Once a prima facie showing of no specific and substantial credible utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration under 37 CFR 1.132 or a printed publication that rebuts the basis or logic of the prima facie showing. If the applicant responds to the prima facie rejection, the Office personnel should review the original disclosure, any evidence relied upon in establishing the prima facie showing, any claim amendments, and any new reasoning or evidence provided by the applicant in support of an asserted specific and substantial credible utility. It is essential for Office personnel to recognize, fully consider and respond to each substantive element of any response to a rejection based on lack of utility. Only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained.

If the applicant satisfactorily rebuts a prima facie rejection based on lack of utility under section 101, withdraw the §101 rejection and the corresponding rejection imposed under section 112, first paragraph.


Q. Todd Dickinson,
Assistant Secretary of Commerce and Commissioner of Patents and Trademarks.

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.
SUMMARY: The Leader, Information Management Group, Office of the Chief Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.
DATES: Interested persons are invited to submit comments on or before January 20, 2000.
ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Danny Werfel, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW, Room 10235, New Executive Office Building, Washington, DC 20503 or should be electronically mailed to the internet address DWERFEL@OMB.EOP.GOV.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency’s ability to perform its statutory obligations. The Leader, Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) title; (3) summary of the collection; (4) description of the need for, and proposed use of, the information; (5) respondents and frequency of collection; and (6) reporting and/or recordkeeping burden. OMB invites public comment.


William E. Burrow,
Leader, Information Management Group, Office of the Chief Information Officer.

Office of Special Education and Rehabilitative Services

Type of Review: Extension.