

rights or obligations of any party. Rather, the guidelines define the procedures to be followed by Office personnel in their review of applications for section 101 compliance. The legal analysis supporting the guidelines articulates the basis for the procedures established in the guidelines. Thus, an applicant who believes his or her application has been rejected in a manner that is inconsistent with the guidelines should respond substantively to the grounds of the rejection. "Non-compliance" with the guidelines will not be a petitionable or appealable action.

Some individuals suggested that the guidelines and legal analysis be amended to specify that the Office will reject an application for lacking utility only in those situations where the asserted utility is "incredible." This suggestion has not been adopted. The Office has carefully reviewed the legal precedent governing application of the utility requirement. Based on that review, the Office has chosen to focus the review for compliance with Section 101 and Section 112, first paragraph, on the "credibility" of an asserted utility.

Some individuals suggested that the guidelines be amended to address how a generic claim that covers many discrete species will be assessed with regard to the "useful invention" requirements of sections 101 and 112 when one or more, but not all, species within the genus do not have a credible utility. The guidelines have been amended to clarify how the Office will address applications in which genus claims are presented that encompass species for which an asserted utility is not credible. The legal analysis makes clear that any rejection of any claimed subject matter based on lack of utility must adhere to the standards imposed by these guidelines. This is true regardless of whether the claim defines only a single embodiment of the invention, multiple discrete embodiments of the invention, or a genus encompassing many embodiments of the invention. As cast in the legal analysis and the guidelines, the focus of examination is the invention as it has been defined in the claims.

Some individuals questioned whether the guidelines and the legal analysis govern actions taken by Examining Groups other than Group 1800 or the Board of Patent Appeals and Interferences. The guidelines apply to all Office personnel, and to the review of all applications, regardless of field of technology.

In addition to the changes made in response to comments from the public,

the Office has amended the guidelines to clarify the procedure to be followed when an applicant has failed to identify a specific utility or an invention. The guidelines now provide that where an applicant has made no assertion as to why an invention is believed useful, and it is not immediately apparent why the invention would be considered useful, the Office will reject the application as failing to identify any specific utility for the invention. The legal analysis has also been amended to address evaluation of this question.

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 application for compliance with the utility requirements of 35 U.S.C. 101 and 112. The guidelines also address issues that may arise during examination of applications claiming protection for inventions in the field of biotechnology and human therapy. The guidelines are accompanied by an overview of applicable legal precedent governing the utility requirement. The guidelines have been promulgated to assist Office personnel in their review of applications for compliance with the utility requirement. The guidelines and the legal analysis do not alter the substantive requirements of 35 U.S.C. 101 and 112, nor are they designed to obviate review of applications for compliance with this statutory requirement.

B. Examination Guidelines for the Utility Requirement

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

1. Read the specification, including the claims, to:

(a) Determine what the applicant has invented, noting any specific embodiments of the invention;

(b) Ensure that the claims define statutory subject matter (e.g., a process, machine, manufacture, or composition of matter);

(c) Note if applicant has disclosed any specific reasons why the invention is believed to be "useful."

2. Review the specification and claims to determine if the applicant has asserted any credible utility for the claimed invention:

(a) If the applicant has asserted that the claimed invention is useful for any

particular purpose (i.e., a "specific utility") and that assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility. Credibility is to be assessed from the perspective of one of ordinary skill in the art in view of any evidence of record (e.g., data, statements, opinions, references, etc.) that is relevant to the applicant's assertions. An applicant must provide only one credible assertion of specific utility for any claimed invention to satisfy the utility requirement.

(b) 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 of a product or obvious application of a process).

(c) If the applicant has not asserted any specific 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 utility for the invention. Also impose a separate rejection under section 112, first paragraph, on the basis that the applicant has not shown how to use the invention due to lack of disclosure of a specific utility. The sections 101 and 112, rejections should shift the burden to the applicant to:

- Explicitly identify a specific utility for the claimed invention, and
- Indicate where support for the asserted utility can be found in the specification.

Review the subsequently asserted utility by the applicant using the standard outlined in paragraph (2)(a) above, and ensure that it is fully supported by the original disclosure.

3. *If no assertion of specific 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 section 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 and should be set out as a rejection distinct from any other