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Legal Update

Utility Patent Guidelines[†]

In 1995, the Patent and Trademark Office ("PTO") promulgated patent examiner guidelines and legal analyses on the utility requirements of sections 101¹ and 112² of the Patent Code, and on the patentability of computer-related inventions. [1]

In response to criticisms of the PTO's treatment of biotechnology patent applications,³ the PTO issued the utility guidelines to address the need for consistency in examining patent applications. Some of the complaints that the PTO received were directed to the examiners, who were requiring human clinical data to establish the statutory requirements of utility for biotechnology inventions. The legal analysis itself emphasizes that any combination of evidence from *in vitro* or *in vivo* testing can be sufficient to establish the credibility of an asserted utility of a patent application. [2]

Other criticisms focused on the fact that experienced patent examiners with less current training in science were reluctant to issue patents in a field where the parameters are uncertain and unfamiliar to them. As issued, the guidelines apply to all personnel at the PTO in review of all applications, regardless of the field of technology.⁴ [3]

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1 35 U.S.C. § 101 (1994).

2 35 U.S.C. § 112 (1994).

3 See Request for Comments on Proposed Utility Examination Guidelines, 60 Fed. Reg. 97 (1995).

4 See Utility Examination Guidelines, 60 Fed. Reg. 36263 (1995).

Under the new guidelines for computer-related inventions, the patent examiners are to presume that: (1) a computer or other programmable apparatus whose actions are directed by a computer program or other form of "software" is a statutory "machine;" (2) a computer-readable memory that can be used to direct a computer to function in a particular manner when used by the computer is a statutory "article of manufacture;" and (3) a series of specific operational steps to be performed on or with the aid of a computer is a statutory "process" within the meaning of section 101.⁵ [4]

The guidelines also expressly declare, however, that the following subject matter, when claimed in a patent application, is non-statutory, and therefore unpatentable: (1) a compilation or arrangement of data, independent of any physical element; (2) a known machine-readable storage medium that is encoded with data representing creative or artistic expression, such as a work of music, art, or literature; (3) a "data structure" independent of any physical element; and (4) a process that does nothing more than manipulate ideas or concepts.⁶ [5]

In addition to the guidelines, the PTO issued its legal analysis to support the examiner guidelines.⁷ This analysis clarifies that examination will no longer begin with a determination of whether a claim recites a mathematical algorithm, but rather, that the PTO will review the complete specification, including the detailed description of the invention, any specific embodiments that have been disclosed, the claims themselves, and finally, the specific utility that has been asserted for the invention. [6]

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⁵ Examination Guidelines for Computer-Related Inventions, 61 Fed. Reg. 7478, 7482 (1996).

⁶ *Id.* at 7481.

⁷ Available on the World Wide Web at <http://www.pto/html>.