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From: Peter K Rogan

Sent: Saturday, June 17, 2006 9:26 PM

To: AB98 Comments

Subject: PTO-2005-0012-0001: Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility

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In the matter of Lab Corp of America Holding vs. Metabolite Laboratories, the issue of patent subject matter eligibility under 35 USC 101 allowed claims on a patent which are factually incorrect in some patients. The claims concern the relationship between homocysteine levels and the likelihood of a exhibiting a medical condition. The levels of homocysteine are not the sole determinant of this medical condition, and patients exist who have the medical condition but normal homocysteine levels. Allowance of patent claims associating a measurement with a phenomenon (in this case, a clinical phenotype) must consider the preponderance of all factors the cause that phenomenon. In many instances (such as this case), a comprehensive catalog of such factors is unknown and the claim may not be correct. A patent is supposed to create knowledge which benefits the the public good. A factually incomplete or inaccurate claim does not benefit anyone and should not be patentable. Unless the inventor proves experimentally that the measurement is the only factor that can explain this phenomenon, then the claim should not be allowed under 35 USC 101.