

From: Klein, Roger [mailto:Roger.Klein@BCW.edu]
Sent: Monday, September 28, 2009 3:20 PM
To: AB98 Comments
Cc: comments@uspto.gov
Subject: Comments on Interim Examination Instructions for Evaluating Patent Subject Matter Eligibility

Dear Ms. Dennison:

Please find attached my comments on the USPTO Interim Examination Instructions for Evaluating Patent Subject Matter Eligibility. Thank you very much for your attention and consideration.

Sincerely,

Roger Klein

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September 28, 2009

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Mr. John J. Doll
Commissioner of Patents
600 Dulany Street
Alexandria, VA 22313

Dear Mr. Doll:

The following comments are in response to the United States Patent and Trademark Office's (USPTO) request for comments on its "Interim Examination Instructions for Evaluating Patent Subject Matter Eligibility."

By way of background, I am a practicing academic molecular pathologist and geneticist who is board certified in both clinical pathology and the subspecialty of molecular genetic pathology. In the practice of my medical specialty, I perform genetic and other molecular pathology testing. In addition, I am a licensed attorney who has participated in appellate litigation at all levels of federal and state courts. My current academic activities include research and publication about legal issues affecting diagnostic laboratories.

My comments are specifically directed toward: sections I, "Subject Matter Eligibility" Steps 1 and 2, "Non-limiting examples of claims that are not directed to one of the statutory categories" and "pre-emption of a law of nature or natural phenomenon" (pages 2 and 3); and II(B) "Particular Practical Application, Processes (methods)" (pages 4 – 6), and are as follows:

The USPTO should include as an example of claims that are not directed to a statutory subject matter category, patent applications that claim the right to exclude others from using or applying biological correlations between genetic variants and phenotypes such as predisposition to disease, responsiveness to therapeutic drugs, or susceptibility to pharmacologic side effects. Unless these types of process claims are tied to specific instruments or encompass true methods, they represent patents on natural phenomena in the purest sense, and preempt all uses of the natural relationships that are the subject of their claims.

Moreover, the USPTO should make it clear that the addition of a broadly claimed amplification step such as a mere PCR reaction to a genetic correlation claim, does not constitute a transformation of matter as set forth by the Federal Circuit in *In re Bilski*, 545 F3d 943 (Fed Cir 2008) (en banc). Such amplification steps do not transform the genetic variant “into a different state or thing,” and more important, “are not central to the purpose of the claimed process.” *Bilski*, 545 F3d at 962. Instead, the intermediary, ancillary, and, because of their routine nature, insignificant functions of such amplification reactions is to increase the number of copies of a genetic variant so that its presence can be detected and the relevant biological correlation made.

However, neither the genetic variant nor the claimed phenotypic relationship has been altered by the aforementioned process. In fact, transforming the variant or correlation would preclude its detection and obviate the purpose of the process. The fundamental difference between juxtaposing in stepwise fashion nucleic acid amplification and biological relationships between variants and phenotypes, and the processes of “tanning, dyeing, making waterproof cloth, vulcanizing India rubber, smelting ores” is that the former series of events directs claims toward ownership of correlations, whereas the latter processes claim methods of creating new or different articles or products. *Bilski*, 545 F3d at 962.

Broadly claimed amplification steps are generically performed to enable detection of naturally occurring genetic variations, which when coupled to steps correlating the variants with relevant phenotypes, constitute claims on natural phenomena. To quote the words of Justice Breyer in his dissent in *LabCorp v. Metabolite Labs*, which are equally applicable in this setting, “At most, respondents have simply described the natural law at issue in the abstract patent language of a ‘process.’” *Laboratory Corp. of Am. v. Metabolite Labs., Inc.*, 126 S.Ct. 2921, 2928 (2006), dismissed as improvidently granted (Breyer, J. dissenting).

Correlation patents on genetic variants and phenotypes impede the growth and development of molecular diagnostic tests that provide information used to predict future disease and to establish diagnosis, prognosis, or the likelihood of responsiveness to individualized therapies. Such patents remove the subject correlations from the public domain, thereby preventing pathologists, geneticists, and other clinical laboratorians from setting up safe, effective, and inexpensive tests to measure them. These patents are analogous to hypothetical patents claiming the relationship between elevated glucose and diabetes, or consolidation on a chest x-ray and pneumonia.

Given that discoveries of genotype-phenotype correlations have historically been made by NIH-funded academic researchers for whom pursue of publications, grants and peer recognition are primary motivators, patent incentives are unnecessary to stimulate research to discover these types of natural phenomena. Moreover, because most molecular genetic tests can be designed and implemented using standard, rightfully patented techniques that are routinely

performed in clinical laboratories (e.g., PCR, real-time PCR, and Sanger sequencing), correlation patents impede the incorporation of molecular genetic tests into medical practice, i.e. ‘commercialization’, by restricting test development and assay introduction in individual diagnostic laboratories.

References:

Klein RD. Medical-Process Patents. N Engl J Med 2007;356:753-754.

Klein RD. Gene Patents and Genetic Testing in the United States. Nat Biotechnol 2007;25:989-90.

Klein RD, Mahoney MJ. LabCorp v. Metabolite Labs: The Supreme Court Listens, but Declines to Speak. J Law Med Ethics 2008;36:141-9.

Thank you very much for your attention and consideration.

Sincerely,

Roger D. Klein

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