The Future of Diagnostic Patents

Rebecca S. Eisenberg
University of Michigan Law School

35 U.S.C. 101 Inventions patentable.

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Laboratory Corp. v. Metabolite Laboratories, 548 U.S. 124 (2006) (Breyer , joined by Souter and Stevens, dissenting)

"A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:

"assaying a body fluid for an elevated level of total homocysteine; and

"correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate."

Bilski v. Kappos (U.S. Supreme Court 2010)

A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of:

(a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase saidcommodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer;

(b) identifying market participants for said commodity having a counterrisk position to said consumers; and

(c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions

Classen v. Biogen (Fed. Cir. 2008)

1. A method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals, which comprises immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens, according to said immunization schedule, and comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group.

Prometheus Laboratories v. Mayo Collaborative Services (Fed. Cir. 2009)

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8x108 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per 8x108 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Ass'n for Molecular Pathology v. U.S. PTO (S.D.N.Y. 2010)

1. A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from a group consisting of the alterations set forth in Tables 12A, 14, 18, or 19 in a human which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO:1.

In re Grams, 888 F.2d 835 (Fed. Cir. 1989)

1. A method of diagnosing an abnormal condition in an individual, the individual being characterized by a plurality of correlated parameters of a set of such parameters that is representative of the individual's condition, the parameters comprising data resulting from a plurality of clinical laboratory tests which measure the levels of chemical and biological constituents of the individual [sic] and each parameter having a reference range of values, *the method comprising*

[a] performing said plurality of clinical laboratory tests on the individual to measure the values of the set of parameters;

[b] producing from the set of measured parameter values and the reference ranges of values a first quantity representative of the condition of the individual;

[c] comparing the first quantity to a first predetermined value to determine whether the individual's condition is abnormal;

[d] upon determining from said comparing that the individual's condition is abnormal, successively testing a plurality of different combinations of the constituents of the individual by eliminating parameters from the set to form subsets corresponding to said combinations, producing for each subset a second quantity, and comparing said second quantity with a second predetermined value to detect a non-significant deviation from a normal condition; and

[e] identifying as a result of said testing a complementary subset of parameters corresponding to a combination of constituents responsible for the abnormal condition, said complementary subset comprising the parameters eliminated from the set so as to produce a subset having said non-significant deviation from a normal condition.

Arrhythmia Research v. Corazonix, 958 F.2d 1053 (Fed. Cir. 1992)

1. A method for analyzing electrocardiograph signals to determine the presence or absence of a predetermined level of high frequency energy in the late QRS signal, comprising the steps of:

   converting a series of QRS signals to time segments, each segment having a digital value equivalent to the analog value of said signals at said time;

   applying a portion of said time segments in reverse time order to high pass filter means;

   determining an arithmetic value of the amplitude of the output of said filter; and

   comparing said value with said predetermined level.