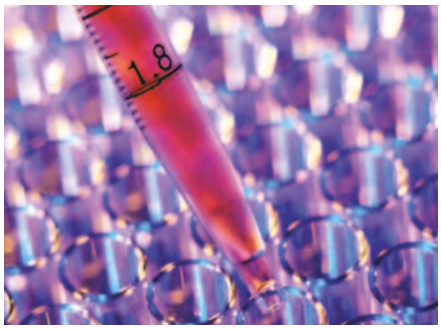
PATENTWATCH



Can making a correlation be patented?

The US Supreme Court recently agreed to review a case in which the simple process of correlating an assay measurement to a medical deficiency could constitute infringement of the patent for the diagnostic test — both directly by the doctors making the diagnosis and indirectly by the companies supplying the tests. The case raises questions about the patentability of "laws of nature, natural phenomena, and abstract ideas" according to the 'natural phenomenon' doctrine.

The suit between Laboratory Corporation of America (LabCorp) and Metabolite Laboratories concerns a patent (USP4,940,658) originally issued to University Patents Inc. (UPI) for a total homocysteine test that can be used to diagnose vitamin B deficiencies. The patent was licensed by UPI's successor, Competitive Technologies, to Metabolite Laboratories, which then sub-licensed the technology to LabCorp (previously Roche Biomedical Laboratories). However, in 1998, LabCorp switched to using a total homocysteine assay developed by Abbott and stopped paying royalties to Metabolite, causing Metabolite to sue LabCorp for infringement and breach of contract. LabCorp argued that the claims of the '658 patent were invalid, but a district court found LabCorp guilty of willfully infringing the patent and intentionally inducing infringement of the patent (by marketing the test to physicians), as well as breaching its licence with Metabolite. The court also ruled that the patent claims were valid and enforceable. The US Court of Appeals for the Federal Circuit later affirmed the rulings by the lower court.

The ongoing argument centres on the language in the subject matter claim (claim 13) of the '658 patent, which describes two steps for the test: assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of total homocysteine in said bodily fluid with a deficiency of cobalamin or folate. It is the use of the term 'correlating' that is now in question — specifically "whether a method patent setting forth an indefinite, undescribed and non-enabling step directing a party to 'correlate' test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about it."

LabCorp petitioned the case to the Supreme Court, claiming that the standard used in this case to show 'intention to induce' infringement was so low that anyone could be termed an 'inducer' simply by providing information about the commonly used diagnostic test. But in a government brief published in August for the Supreme Court, the US Patent and Trademark Office (USPTO) concluded that the record of the case was not sufficiently developed with regard to facts required to resolve the validity of claim 13 under the 'natural phenomenon' doctrine, and that the case "does not provide an appropriate vehicle for examining such a fundamentally important issue." However, on 31 October, against USPTO advice and amid suggestions that the USPTO wishes to avoid reexamination of a defective patent, the Supreme Court announced that the case would be reviewed. The outcome could have significant implications for existing patents on diagnostic tests and for the future issue of technology patents in the US.

Joanna Owens

***Metabolite Labs versus Laboratory Corp. of America*:**
http://www.aipla.org/html/reports/2005/LabCorpCAFC.pdf
http://wwwaipla.org/html/reports/2005/LabCorpGovAmicus.pdf