

*Will Patent
Claims Containing
Mental Steps
Be Invalidated
By the Supreme
Court?*

On October 31, the Supreme Court granted certiorari on whether a patent claim which includes the step of “correlating,” which can be performed in a person’s head, is patentable subject matter. The patent claim in question is directed to a method of analyzing for certain amino acids in body fluids:

13. 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.

U.S. Patent No. 4,940,658, column 41, lines 58–65. The inventors discovered that high levels of total homocysteines indicated cobalamin or folic acid deficiency, which in turn indicates hematologic abnormalities such as anemia. The specific question that the Court decided to review seems to focus on the propriety of including a mental step in the claim:

Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to “correlate[e]” 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 the relationship after looking at a test result.

Order Granting Certiorari at 1 (No. 04–607) (emphasis added). This question implicates the old “mental steps” doctrine. Under the “mental steps” doctrine, a method claim which included a step which was to be performed in the mind of a person was not patentable subject matter. This prohibition was largely eliminated by a series of Federal Circuit decisions. However, the Court asked the Solicitor General about validity of the claim not based on the “mental steps” doctrine but based on laws of nature:

The Solicitor General is invited to file a brief in this case expressing the views of the United States, limited to the following question: Respondent’s patent claims a method for detecting a form of vitamin B deficiency, which focuses upon a correlation in the human body between elevated levels of certain amino acids and deficient levels of vitamin B. The method consists of the following: First, measure the level of the relevant amino acids using any device, whether the device is, or is not, patented; second, notice whether the amino acid level is elevated and, if so, conclude that a vitamin B deficiency exists. Is the patent invalid because one cannot patent “laws of nature, natural phenomena,

and abstract ideas?” *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

Order, February 25, 2005. (emphasis added).

The Solicitor General recommended that the Court should not grant certiorari in this case because neither the record nor legal arguments have been developed below:

The record is not sufficiently developed to permit comprehensive consideration of the question whether claim 13 satisfies the subject matter requirements of Section 101.

Brief for the United States as Amicus Curiae at 9. The Solicitor pointed out that in the proceedings below, the petitioner did not even assert or argue invalidity based on the claim not being within statutory subject matter:

The Petitioner did not challenge the validity of claim 13 under the natural phenomenon doctrine in either of the lower courts, and neither of those courts addressed the question. Indeed, petitioner did not mount any challenge, under any theory, to the patentability of the claimed subject matter under Section 101.

Id. at 15. The Solicitor cautioned the Court that a large number of patents could be affected by the Court’s decision:

A decision overturning PTO’s approach could call into question a substantial number of patent claims

and undermine the settled expectations of numerous participants in technology-based industries.

Id. at 14.

The number of patent claims that would be invalidated by a reversal of the Federal Circuit’s understanding of *Flook and Diehr* is difficult to predict, and would depend in part on the rule of law adopted by this Court. At a minimum, however, a paradigm shift in the way PTO and the lower courts have viewed *Diehr* would engender substantial uncertainty.

Id. at 15 n.*.

The Supreme Court nevertheless granted certiorari and is likely to decide the case in the Spring 2006 term. It appears that the Supreme Court is anxious to address the question of whether claims which include mental steps are patentable and may well change the existing law. To the extent the Supreme Court’s anxiety about the issue is based on a doctor infringing merely by making a diagnosis, the Court seems to be overlooking the exemption for a medical practitioner’s performance of a medical activity provided by section 287(c) of the Patent Statute. Reversal of the existing law could lead to the invalidity of literally thousands of patents in many fields of technology ranging from diagnostics and chemical processes to business methods.

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