

Review and Analysis of Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., No. 04-607, SUPREME COURT OF THE UNITED STATES, 2006 U.S. LEXIS 4893; 74 U.S.L.W. 4431; 79 USPQ2d 1065; 19 Fla. L. Weekly Fed. S 311, Decided June 22, 2006

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I. SUMMARY

This case has to do with "correlation" claims, particularly for medical technology, but applicable to other technologies as well. In addition, it provides useful guidance on how the Supreme Court will receive the Court of Appeals for the Federal Circuit's "useful, concrete, and tangible result" test for compliance with 35 USC 101.

II. FACTS

In this case, the Supreme Court granted cert., and then dismissed (a "DIG"; Dismissal for Improvident Grant of Certiori). The Supreme Court concluded that the issue raised in the appellant's brief had not been argued in the courts below (district court and Federal Circuit), and therefore was not entitled to consideration. The issue raised by the appellants in their brief to the Supreme Court was whether claim 13 met the 35 USC 101 requirement for statutory subject matter, and did not claim merely a law of nature. Although the Supremes DIG'd this case, the Chief Justice did not participate, and there was a three Justice dissent (Justices Breyer, Stevens and Souter). The dissent's opinion explains why it dissents, but more importantly, explains why on the merits it would have held claim 13 invalid. Since the views of the other 5 justices on the merits are unknown, it may be that the opinion of the dissent, on the merits, is a majority view of the Court! Hence, it is instructive to review the claim at issue, and the reasons why the dissent would have found this claim unpatentable. Claim 13 reads as follows:

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.

Both parties construed "correlating" to read upon the mental impression of a doctor recognizing that the level identified by the assay was "an elevated level of total homocysteine" compared to a normal level of total homocysteine. It was also established that, since the normal level of total homocysteine was well known, any doctor seeing a result of an assay for total homocysteine would immediately recognize if that level was an elevated level. Under those facts, the dissent opined on whether claim 13 was 35 USC 101 statutory subject matter as follows:

I turn to the merits. The researchers who obtained the present patent found that an elevated level of homocysteine in a warm-blooded animal is correlated with folate and cobalamin deficiencies. As construed by the Federal Circuit, claim 13 provides those researchers with control over doctors' efforts to use that correlation to diagnose vitamin deficiencies in a patient. Does the law permit such

protection or does claim 13, in the circumstances, amount to an invalid effort to patent a "phenomenon of nature"?

I concede that the category of non-patentable "phenomena of nature," like the categories of "mental processes," and "abstract intellectual concepts," is not easy to define. See Flook, supra, at 589, 98 S. Ct. 2522, 57 L. Ed. 2d 451 ("The line between a patentable 'process' and an [*17] unpatentable 'principle' is not always clear"); cf. Nichols, 45 F.2d at 122 ("We are as aware as anyone that the line [between copyrighted material and non-copyrightable ideas], wherever it is drawn, will seem arbitrary"). After all, many a patentable invention rests upon its inventor's knowledge of natural phenomena; many "process" patents seek to make abstract intellectual concepts workably concrete; and all conscious human action involves a mental process. See generally 1 Chisum 1.03, at 78-295. Nor can one easily use such abstract categories directly to distinguish instances of likely beneficial, from likely harmful, forms of protection. Cf. FTC, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, ch. 3, p. 1 (Oct. 2003) (hereinafter FTC) (collecting evidence that "issues of fixed cost recovery, alternative appropriability mechanisms, and relationships between initial and follow-on innovation" vary by industry); Burk & Lemley, Policy Levers in Patent Law, 89 Va. L. Rev. 1575, 1577-1589 (2003) ("Recent evidence has demonstrated that this complex relationship [between patents and innovation] is . . . industry-specific [*18] at each stage of the patent process").

But this case is not at the boundary. It does not require us to consider the precise scope of the "natural phenomenon" doctrine or any other difficult issue. In my view, claim 13 is invalid no matter how narrowly one reasonably interprets that doctrine.

There can be little doubt that the correlation between homocysteine and vitamin deficiency set forth in claim 13 is a "natural phenomenon." That is what the petitioners argue. It is what the Solicitor General has told us. Brief for United States as Amicus Curiae 19 (filed Dec. 23, 2005) ("The natural relationship between elevated homocysteine and deficiencies in the B vitamins is an unpatentable 'principle in natural philosophy or physical science'" (quoting Morse, 15 How., at 116, 56 U.S. 62, 14 L. Ed. 601)). Indeed, it is close to what the respondents concede. Brief for Respondents 31 ("The correlation between total homocysteine and deficiencies in cobalamin and folate that the inventors discovered could be considered, standing alone, a 'natural phenomenon' in the literal sense: It is an observable aspect of biochemistry in at least some human populations").

The respondents argue, however, that [*19] the correlation is nonetheless patentable because claim 13 packages it in the form of a "process" for detecting vitamin deficiency, with discrete testing and correlating steps. They point to this Court's statements that a "process is not unpatentable simply because it contains a law of nature," Flook, 437 U.S., at 590, 98 S. Ct. 2522, 57 L. Ed. 2d 451; see also Gottschalk, 409 U.S., at 67, 93 S. Ct. 253, 34 L. Ed. 2d 273, and that "an application of a law of nature . . . to a known . . . process may well be deserving of patent protection." Diehr, 450 U.S., at 187, 101 S. Ct. 1048, 67 L. Ed. 2d 155.

They add that claim 13 is a patentable "application of a law of nature" because, considered as a whole, it (1) "entails a physical transformation of matter," namely, the alteration of a blood sample during whatever test is used, Brief for Respondents 33 (citing Cochrane v. Deener, 94 U.S. 780, 788, 24 L. Ed. 139, 1877 Dec. Comm'r Pat. 242 (1877); Gottschalk, supra, at 70, 93 S. Ct. 253, 34 L. Ed. 2d 273), and because it (2) "produces a 'useful, concrete, and tangible result,'" namely, detection of a vitamin deficiency, Brief for Respondents 36 (citing State Street Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368, 1373 (CA Fed 1998)). [*20]

In my view, however, the cases to which respondents refer do not support their claim. Neither Cochrane nor Gottschalk can help them because the process described in claim 13 is not a process for transforming blood or any other matter. Claim 13's process instructs the user to (1) obtain test results and (2) think about them. Why should it matter if the test results themselves were obtained through an unpatented procedure that involved the transformation of blood? Claim 13 is indifferent to that fact, for it tells the user to use any test at all. Indeed, to use virtually any natural phenomenon for virtually any useful purpose could well involve the use of empirical information obtained through an unpatented means that might have involved transforming matter. Neither Cochrane nor Gottschalk suggests that that fact renders the phenomenon patentable. See Cochrane, supra, at 785, 24 L. Ed. 139, 1877 Dec. Comm'r Pat. 242 (upholding process for improving quality of flour by removing impurities with blasts of air); Gottschalk, supra, at 71-73, 93 S. Ct. 253, 34 L. Ed. 2d 273 (rejecting process for converting numerals to binary form through mathematical formula).

Neither does the Federal Circuit's decision in [*21] State Street Bank help respondents. That case does say that a process is patentable if it produces a "useful, concrete, and tangible result." 149 F.3d at 1373. But this Court has never made such a statement and, if taken literally, the statement would cover instances where this Court has held the contrary. The Court, for example, has invalidated a claim to the use of electromagnetic current for transmitting messages over long distances even though it produces a result that seems "useful, concrete, and tangible." Morse, supra, at 116, 56 U.S. 62, 14 L. Ed. 601. Similarly the Court has invalidated a patent setting forth a system for triggering alarm limits in connection with catalytic conversion despite a similar utility, concreteness, and tangibility. Flook, supra. And the Court has invalidated a patent setting forth a process that transforms, for computer-programming purposes, decimal figures into binary figures -- even though the result would seem useful, concrete, and at least arguably (within the computer's wiring system) tangible. Gottschalk, supra.

Even were I to assume (purely for argument's sake) that claim 13 meets certain general definitions of [*22] process patentability, however, it still fails the one at issue here: the requirement that it not amount to a simple natural correlation, i.e., a "natural phenomenon." See Flook, supra, at 588, n. 9, 98 S. Ct. 2522, 57 L. Ed. 2d 451 (even assuming patent for improved catalytic converter system meets broad statutory definition of patentable "process," it is invalid under natural phenomenon doctrine); Diehr, 450 U.S., at 184-185, 101 S. Ct. 1048, 67

L. Ed. 2d 155 (explaining that, even if a patent meets all other requirements, it must meet the natural phenomena requirement as well).

At most, respondents have simply described the natural law at issue in the abstract patent language of a "process." But they cannot avoid the fact that the process is no more than an instruction to read some numbers in light of medical knowledge. Cf. *id.*, at 192, 101 S. Ct. 1048, 67 L. Ed. 2d 155 (warning against "allowing a competent draftsman to evade the recognized limitations on the type of subject matter eligible for patent protection"). One might, of course, reduce the "process" to a series of steps, e.g., Step 1: gather data; Step 2: read a number; Step 3: compare the number with the norm; Step 4: act accordingly. But one can reduce any process [*23] to a series of steps. The question is what those steps embody. And here, aside from the unpatented test, they embody only the correlation between homocysteine and vitamin deficiency that the researchers uncovered. In my view, that correlation is an unpatentable "natural phenomenon," and I can find nothing in claim 13 that adds anything more of significance.

III. ANALYSIS

A. Merits of the dissent's analysis

I disagree with the dissent on the merits because their conclusion that claim 13 fails 35 USC 101 is directed to only the "correlating" step, and not to the claim as a whole. More specifically, the dissent failed to recognize that "assaying" is a physical mechanical process, and therefore any claim including a step of "assaying", regardless of what else the claim recites, meets the requirements for statutory subject matter. That being said, there are important guidelines provided by dissent that are of great significance in predicting how the court would handle other cases relating to 35 USC 101.

B. Guidance on the Future of the "useful, concrete, and tangible result" Test

The dissent impugns the State Street Bank decision's "useful, concrete, and tangible result" by noting that it is inconsistent with Morse, Flook, and Gottschalk, and by noting that the "useful, concrete, and tangible result" test is not Supreme Court precedent. The dissent represents the opinion of three members of the Court on the "useful, concrete, and tangible result" test, and the opinion of the other five members of the Court is not currently known. Thus, the odds are that the Supreme Court would not affirm that the "useful, concrete, and tangible result" test is an appropriate test for 35 USC 101 statutory subject matter.

C. Mental "correlation" Limitations

Where does this leave "correlation" limitations where the correlation is one of mental impression? In limbo. However, it would be wise to include alternative claims including limitations other than a mere mental impression correlation. For example, alternatives to claim 13 might have included printing or displaying (1) the result of the assay for total homocysteine and (2) a normal range for total homocysteine. Since most medical tests display a normal range along with any test results, such a backup claim could have mooted the 35 USC 101 challenge of this case. Moreover, details of the process of assaying could have been claimed.

D. Were the Right Issues Raised at the Trial Level?

Finally, it is not clear that the patent infringement defendant argued the right issue at the trial level. Specifically, it is not clear that the defendant argued that claim 13 was invalid due to

anticipation or obviousness on the theory (1) that the assaying step was well known, and (2) that the step of correlating was not a distinguishing limitation since it only required a mental impression. If it had, the outcome at the trial level might have been different.

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