No. 04-607

IN THE

Supreme Court of the United States

LABORATORY CORPORATION OF AMERICA HOLDINGS, DBA LABCORP,

Petitioner,

v.

METABOLITE LABORATORIES, INC., ET AL.

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF PATIENTS NOT PATENTS, INC., AS AMICUS CURIAE IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to "correlate[e]" 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.

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INTEREST OF AMICUS CURIAE[1]

Amicus curiae Patients not Patents (PNP)[2] is a nonprofit organization dedicated to ensuring access to healthcare through litigation, advocacy, and education. PNP is organized around the principle that medical treatment should not be denied or restricted because of the existence of patents or other intellectual property barriers. Over the past year, PNP has had success in challenging the validity of patents on drugs owned by pharmaceutical companies through administrative proceedings at the U.S Patent and Trademark Office. Additionally, PNP protects consumer interests by conducting litigation against makers of dietary supplements for false advertising—specifically falsely marking unpatented products as patented.

PNP has an interest in this case because the Court's decision will have a significant effect on intellectual property barriers to health care. PNP also has an interest in this case because it will affect PNP's success in administratively challenging patents before the USPTO.

SUMMARY OF ARGUMENT

The claim at the center of the controversy between LabCorp and Metabolite is directed to a mental process for recognizing that a natural phenomenon has occurred. Because neither mental processes nor natural phenomena are pat-

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[1] Letters of consent to the filing of this brief from all parties have been filed with the Clerk. This brief was not authored in whole or in part by counsel for a party. No person or entity other than amicus curiae, its members, or its counsel made a monetary contribution to preparation or submission of this brief.

[2] Patients not Patents, *at* http://www.patientsnotpatents.org.

entable subject matter, the claim is invalid. Upholding the claim would lead to a proliferation of patents for purely mental processes, which would in turn harm both individual patients as well as public health.

ARGUMENT

I. UPHOLDING THIS PATENT WILL OPEN THE FLOODGATES FOR PATENTS CONTAINING MENTAL STEPS

If this Court finds that Claim 13 is directed to patentable subject matter, this Court will broaden the scope of what may be patentable to cover subject matter that had been previously unpatentable. Since the Federal Circuit ruled against LabCorp in June of 2004, the United States Patent and Trademark Office has received an increasing number of applications drawn to what had been considered by many patent practitioners as nonstatutory subject matter.[3] Some of these mirror the structure of Claim 13:

"A method for determining the prognosis of a patient suffering from cancer . . . the method comprising . . . *correlating* the tubulin isotype level with an indication of unfavorable prognosis . . . or . . . favorable prognosis" (2005/0272824, Claim 1) (emphasis added). This claim language illustrates how applicants may try to claim a monopoly where the out-

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[3] *See, e.g.*, published patent applications: 2005/0260680, 2005/0260654, 2005/0255537, 2005/0255484, 2005/0244890, 2005/0214760, 2005/0191664, 2005/0095591, 2005/0130230, 2005/0130233, 2005/0262031, 2005/0260683, 2005/0250162, 2005/0171432, 2005/0142618, 2005/0130250, 2005/0130250, 2005/0106104, 2005/0095579, *available at* http://www.uspto.gov.

come of the correlation only speaks to a vague unfavorable or favorable result.

"A method of evaluating a risk of occurrence of a medical condition in a patient, the method comprising: *receiving a patient dataset* for the patient; and *evaluating the dataset with a model predictive of the medical condition*" (2005/0262031, Claim 1) (emphasis added). Here, the applicant even eliminates Claim 13's modest limitation, "assaying." Instead, the claim, as drafted, would encompass the receipt of data by any means. Thus, the claim language seeks protection not just for the interpretation of one test, or the diagnosis of one disease, but for a general strategy of practicing medicine.

"A method for detecting and diagnosing neural injury and/or neuronal disorders comprising: *detecting* at least one or more proteolytic enzyme biomakers. . . and; *correlating the detection* of one or more protein biomarkers with a diagnosis of neural injury and/or neuronal disorders, wherein the *correlation takes into account the detection* of one or more protein biomarkers in each diagnosis, *as compared to normal subjects*" (2005/0260697, Claim1) (emphasis added). Here, the claim is not specific to any defined relationship between test result and a disease.

Further, the decision to uphold the validity of this claim may have broader reach than is initially evident. To meet constitutional requirements, the Court of Customs and Patent Appeals, predecessor to the Federal Circuit, whose opinions are considered *en banc* authority within the Federal Circuit, limited statutory subject matter in a process patent to the technological arts. *In re Musgrave*, 431 F.2d 882, 893 (C.C.P.A. 1970). This Court has never explicitly adopted such a standard.[4] *Amicus* asks the Court to bear this addi-

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[4] Justice Stevens mentioned the "technological arts" standard in his dissent in *Diamond v. Diehr*, 450 U.S. 175, 200 (1981).

tional factor in mind when considering whether to expand the scope of patentable subject matter.

II. INDIVIDUAL PATIENTS WILL BE HARMED BY UPHOLDING CLAIM 13

Upholding Claim 13 as valid will interfere with the doctor-patient relationship. Testing for homocysteine alone does not infringe the patent. But it does produce results that someone, such as a doctor, has to interpret for the data to be meaningful in a clinical context. Interpreting the results alone does not infringe the patent, but someone has to order the assay. A doctor who orders an assay and analyzes whether the natural phenomenon–the correlation between homocysteine and vitamin deficiency–occurred, may infringe Claim 13, as the lower courts' decisions indicate. *E.g., Metabolite Labs., Inc. v. Lab. Corp.*, No. 99-Z-870 (D. Colo. Dec. 3, 2001), *aff'd by Lab. Corp. v. Metabolite Labs., Inc.*, No. 03-1120 (Fed. Cir. Jun. 8, 2004). Thus, even if the doctor orders the test and receives the raw data, he or she may choose to provide the patient with the data, rather than interpret it, to avoid infringement liability.

Increasingly, patients are looking to Internet web pages for help in understanding their health status. Unfortunately, patients are likely to misinterpret the raw data to which they do have access. A proactive patient may, for example, discover a web page that discloses a relationship between total homocysteine levels and vitamin B12 or folic acid deficiency. However, the information on that web page may be incorrect, incomplete, or misunderstood by the patient. The patient's physician may be reluctant to discuss the matter with the patient for fear of creating evidence that he or she correlated the test results with a deficiency of vitamin B12 or folate, thereby infringing on the patent. Thus, Claim 13

harms patients by inhibiting honest communication with their physician.

Although 35 USC § 287(c) limits the liability of a medical practitioner performing a medical activity from patent infringement,[5] the statute would not apply to the claim in controversy. First, the patent in question is based on an application having an effective filing date before Sept. 30, 1996, and is therefore exempt under § 287(c)(4). Second, subsection 2(a) defines "medical activity" as "the performance of the medical or surgical procedure on the body." Because Claim 13 is not directed to a procedure to be performed on the body, the physician may be subject to suit by the patentee.

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[5] § 287(c) provides: (c) (1) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title [35 USCS § 271(a) or (b)], the provisions of sections 281, 283, 284, and 285 of this title [35 USCS §§ 281, 283, 284, and 285] shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity. (2) For the purposes of this subsection: (A) the term "medical activity" means the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent. (B) the term "medical practitioner" means any natural person who is licensed by a State to provide the medical activity described in subsection (c)(1) or who is acting under the direction of such person in the performance of the medical activity. . . . (E) the term "body" shall mean a human body, organ or cadaver, or a nonhuman animal used in medical research or instruction directly relating to the treatment of humans. (4) This subsection shall not apply to any patent issued based on an application the earliest effective filing date of which is prior to September 30, 1996.

III. PUBLIC HEALTH RESEARCH AND INTERVENTIONS ARE HARMED BY PATENTS ON INTERPRETING MEDICAL TESTS

One of the strategies used by public health researchers to determine the cause of disease is an examination of the incidence and prevalence of the disease in different populations. G. Rose, *Sick Individuals and Sick Populations*, Int'l J. of Epidemiology 14, 32-38 (1985), *reprinted in* Gostin, *Public Health Law and Ethics: A Reader*, 58-66 (2002). In contrast, studies which seek to determine why a particular patient has become sick are generally considered individual-centered studies. It is apparent that the availability and cost of licenses for the method described in Claim 13 would impact a physician's determination as to whether a particular patient's symptoms are caused by a deficiency of either vitamin B12 or folate. However, the cost and availability of licenses for the patented method would also affect the ability of researchers to perform population-based studies.[6]

For example, studies of total homocysteine levels in members of different populations have revealed an increased prevalence of folate deficiency in African-American elderly women compared to white elderly women. Stabler, *Racial Differences in Prevalence of Cobalamin and Folate Deficiencies in Disabled Elderly Women. See also* T.G. DeLoughery, G.T. Gerhard, A. Evans, et al., *Elevated Homocyst(e)ine (Hcy) Levels in Premenopausal Black Women are Due to Nutritional and not Genetic Factors.* Blood 88, 471 (1996)(abstr). The prevalence of B12 and folate deficiency has also been studied in connection with income, education, sex, military service and other socioeconomic conditions. S.J.

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[6] Epidemiologists are not protected by 35 U.S.C. 287(c) because their analysis does not constitute a "medical activity."

Bradley, R.L. Sacco, J.K. Roberts, et al. *Race-Ethnicity and Other Environmental Determinants of Serum Homocysteine in Northern Manhattan.* Stroke 29, 277 (1998) (abstr).

The statistical analysis in each of these studies contributes to society's understanding of the disease. Should each of the multitudes of factors found to correspond with deficiency, however weak the connection, be nevertheless patentable? If so, each newly identified risk factor would inhibit, rather than enhance, research conducted through standard analytic tools such as multivariate regression models. On the other hand, it would be contrary to precedent for the determination of patentable of subject matter under 35 U.S.C. § 101 to depend on the strength of the correlation between two or more variables. "Either the subject matter falls within Section 101 or it does not." *Animal Legal Defense. Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991).

CONCLUSION

The threat posed by patent applicants to individual patients and the public health and research is real. Amicus Curiae asks the Court to find Claim 13 invalid under 35 USC §101 as claiming unpatentable subject matter.

Respectfully submitted,

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