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From: White, Tracy (NIH/OD) [E]

Sent: Monday, July 31, 2006 4:03 PM

To: AB98 Comments

Cc: Rohrbaugh, Mark (NIH/OD) [E]

Subject: FW: NIH's Comments to the USPTO's Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility

Attention: Linda Therkorn

On behalf of Mark L. Rohrbaugh, Director, Office of Technology Transfer, National Institutes of Health (NIH), attached please find NIH's comments (in PDF format) to the USPTO's Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, published at 1300 Off. Gaz. Pat. Office 142 (November 22, 2005).

Should you have any difficulty viewing the attached document, please do not hesitate to contact me at whitever@od.nih.gov and/or 301-594-7700. Thank you for the opportunity to submit comments.

Sincerely,

Tracy

Tracy White

Secretary to the Director – Mark Rohrbaugh, Ph.D., J. D.

Secretary to the Deputy Director - Bonny Harbinger, Ph.D., J.D.

Office of Technology Transfer

6011 Executive Boulevard, Suite 325

National Institutes of Health

Rockville, Maryland 20852-38004

(301) 594-7700 Office

(301) 402-9769 Fax

Mail Stop Code: 7660

whitever@od.nih.gov



July 31, 2006

VIA ELECTRONIC MAIL

John J. Doll
Commissioner for Patents
Mail Stop Comments-Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Attn: Linda Therkorn

Dear Commissioner Doll:

The written remarks presented herein are directed to the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (Interim Guidelines), which were set forth at 1300 Off. Gaz. Pat. Office 142 (Nov. 22, 2005) and for which a Request for Comments and an Extension of the Comment Period were published at 70 Fed. Reg. 75,451 (Dec. 20, 2005) and 71 Fed. Reg. 34,307 (Jun. 14, 2006), respectively. These comments represent the views of the National Institutes of Health (NIH).¹

NIH recognizes that the USPTO has published these comprehensive Interim Guidelines to assist USPTO personnel in analyzing claimed subject matter under 35 U.S.C. §101, (Section 101), thereby improving the patent examination process. NIH notes that the USPTO has expressed particular interest in, *inter alia*, “[w]hat role should preemption have in the determination of whether a claimed invention is directed to a practical application of a [Section 101] judicial exception.” 70 Fed. Reg. at 75,452. The comments herein are offered to provide an alternative analysis that hopefully will assist

¹ NIH is the lead agency within the Department of Health and Human Services (HHS) in matters of technology transfer. In addition to providing patent and licensing services to all Institutes and Centers within NIH and the U.S. Food and Drug Administration (FDA), it is the lead agency responsible for coordinating and facilitating technology transfer policy functions for NIH, FDA, and Centers for Disease Control and Prevention (CDC). The Bayh-Dole Act of 1980 (Pub. L. No. 96-517, 94 Stat. 3015, as amended) permits recipients of federal grants and contracts to retain title to their inventions developed under such federal funding. In October 1986, Congress also enacted the Federal Technology Transfer Act (FTTA, Pub. L. 99-502, 100 Stat. 1785), which amended the Stevenson-Wydler Innovation Act of 1980. The FTFA, as amended, stimulates transfer of Government-owned technology by offering incentives to both federal laboratories/scientists and collaborating partners in universities, foundations, and private industry.

the USPTO in examining patent applications that adapt natural phenomena to tangible processes that benefit the public.

Introduction

Scientific advancements in the medical, biologic, and pharmaceutical areas routinely flow from the observation of a correlation between (1) a law of nature or natural phenomenon (i.e., a judicial exception to Section 101) and (2) symptoms, diseases, and other medical conditions. Medical diagnostics and other assays that depend on the aforementioned correlations are numerous, and include, for example, the prostate-specific antigen test for prostate hyperplasia, cholesterol screening tests as indicators of heart disease, and blood glucose tests that, e.g., are indicators of diabetes.

The NIH supports a balanced approach to intellectual property. In instances where further developmental efforts and private sector investment are needed to realize the potential of a basic research observation, access to the incentives provided by the patent system for, *inter alia*, diagnostic methods and assays, serves to foster private sector investment. This is balanced against the widespread public benefit that is garnered by public disclosure and widespread availability of information and technologies where the breadth of exclusivity provided by the patent system is not a requisite for commercial development.²

In the context of this balanced approach to intellectual property, we express concern regarding the preemption analysis proposed in the Interim Guideline as applied to the patenting of diagnostic methods and assays. Indeed, patent applications directed to diagnostic methods and assays typically recite claim limitations that may be characterized as or at least implicate a Section 101 judicial exception. Therefore, the application of the Interim Guidelines to the examination of patent applications drawn to, *inter alia*, diagnostic methods that include or recite a so-called “natural phenomenon” has direct effects upon public health matters.

I. Section 101/Preemption: Background

The proposed Interim Guidelines appropriately emphasize the longstanding doctrine that the claim as a whole must be considered when evaluating patentability under Section 101. This doctrine was set out by the Supreme Court in Diamond v. Diehr, 450 U.S. 175 (1981), in which the Court discussed the eligibility of claims directed to a process for curing rubber:

In determining the eligibility of respondents' claimed process for patent protection under Sec. 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly

² See Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice (the “NIH’s Research Tools policy”), 64 Fed. Reg. 72,090 (December 23, 1999).

true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.

Id., 450 U.S. at 188.

However, prior to the U.S. Supreme Court's decision in Diehr, the Supreme Court, in Parker v. Flook, 437 U.S. 584 (1978), provided that "the discovery of [a natural] phenomenon cannot support a patent unless there is some other inventive concept in its application." Flook, 437 U.S. at 594. That is, one interpretation of Flook would render unpatentable, under Section 101, subject matter that merely set forth a "relationship that always existed" as a natural phenomenon even though the applicant (1) claimed a method that included either a transformation of matter or a substantive additional process step and (2) did not preempt every substantial practical application of the natural phenomenon. Id. at 593 fn.15. That is, under at least one view of Flook, the claim, as a whole, must encompass an inventive concept other than the natural phenomenon. See id. at 594-95. Notably, the Diehr Court stated that Flook "stand[s] for no more than [the] long-established principles" that "laws of nature, natural phenomena, and abstract ideas" are not patentable subject matter. Diehr, 450 U.S. at 185.

Some commentators suggested that any perceived or actual tension between Diehr and Flook was ripe for reconsideration by the U.S. Supreme Court and that the case of Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc., S. Ct. No. 04-607 (LabCorp) would provide an appropriate venue for resolution of the issue.³ However, the U.S. Supreme Court recently dismissed the writ of certiorari in LabCorp as improvidently granted. See id., 548 U.S. __ (June 22, 2006) (*per curiam*). Notwithstanding, we believe that the establishment of appropriate examination guidelines by the USPTO provides an adequate means of providing practical reconciliation of the apparent discord among case law applicable to claims to diagnostic methods based on new scientific observations and correlations.

II. General Comments to Preemption Analysis under Section IV.C.3 of the Interim Guidelines

Section IV.C.3 of the Interim Guidelines provides that the examiner will "determine whether the claimed invention preempts an abstract idea, law of nature, or natural phenomenon (Section 101 Judicial Exceptions)." Section IV.C.3 further provides that "[i]f an examiner determines that the claimed invention preempts a [Section] 101 judicial exception, the examiner must identify the abstraction, law of nature, or natural phenomenon and *explain why the claim covers every substantial practical application thereof.*" (Emphasis added).

Effectively, the guidelines require the examiner to prove a negative. We believe that it would be impossible for the examiner to prove that any claim covers every substantial practical application of the invention.

³ In LabCorp, the validity of a claim to a broad diagnostic method was disputed.

This requirement would subject examiners to time-consuming efforts that fail to yield meaningful assessments as to the preemption issue for claimed inventions. And, under the Interim Guidelines, as illustrated in the flow chart in Annex I, delay in the preemption analysis stalls advancement of the application through the prosecution process. In addition, the establishment of an untenable examination standard may result in issuing more patent claims of undue breadth.

III. Framework for Preemption Analysis

As the Interim Guidelines provide, the analysis of Section 101 patentability begins with an analysis of the claim as a whole. In doing so, the examiner considers all steps or limitations in the claim to determine whether these steps or limitations cause the claim to fall within the scope of statutory subject matter, i.e., whether the steps or limitations distinguish the claimed subject matter from a Section 101 judicial exception. A Section 101 exception may also encompass “mental steps.”

We propose that the initial focus of examination should not simply be the Section 101 exception itself, but the fundamental question of whether the claimed subject matter is novel under 35 U.S.C. §102, i.e., whether it does not seek to remove from the public domain that which has come before. The issues of Section 101 judicial exception and novelty are inevitably intertwined since a phenomenon of nature is, by definition, not novel even if its existence was not recognized. Therefore, by focusing on the question of novelty in the evaluation of the patentability of any claimed subject matter encompassing a Section 101 judicial exception, the framework for examination would be more objective and practical than that described *infra* at II.

A specific example arises from LabCorp, in which a diagnostic method claim in U.S. Patent No. 4,940,658 (the '658 patent) was at issue.⁴ The diagnostic method claim, Claim 13 recites:

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.

'658 patent, col. 41, ll. 58-65 (Emphasis added). Claim 13 encompasses a mental step, i.e., the correlating step, such that, under the proposed framework, analysis of the initial

⁴ We recognize that the U.S. Supreme Court's dismissal of the writ of certiorari in LabCorp leaves intact the decision by the U.S. Court of Appeals for the Federal Circuit, which held, *inter alia*, that Claim 13 was infringed and was valid under 35 U.S.C. §§ 102, 103 and 35 U.S.C. § 112, ¶¶ 1, 2. See Metabolite Laboratories, Inc. v. Laboratory Corp. of America, 370 F.3d 1354 (Fed. Cir. 2004). Therefore, our discussion of Claim 13 herein is directed to providing an example of a diagnostic method claim so as to highlight policy implications of preemption analysis and *does not* constitute any legal opinion.

patentability of the claim by an examiner would focus on whether the additional correlating step of Claim 13 distinguishes the claim from the natural phenomenon (the correlation) or that which has come before.

More generally, under the foregoing method of analysis, where a claimed invention for a diagnostic method includes a limitation that falls under a Section 101 exception (e.g., a mental step), the examiner would evaluate the claim as whole, including the mental step limitation, to determine whether the additional step modifies the claimed physical, tangible process(es) so as to distinguish the claimed subject matter from the natural phenomenon or that which has come before.

The examiner, however, need not give any patentable weight to the mental step for purposes of discerning whether the claimed process is novel or nonobvious, absent a new and unobvious functional relationship between either (a) the mental step and the operation of the claimed process (i.e. the operation or function of the tangible process step(s)) or (b) the mental step and the function of the claimed product.

This proposed framework for preemption analysis of claimed subject matter is analogous to precedent applied to analysis of claims encompassing printed matter. Annex IV of the Interim Guidelines, which is directed to Computer-Related Nonstatutory Subject Matter, acknowledges the significance of this precedent in the context of evaluating the patentability of claimed computer-related inventions incorporating nonfunctional descriptive material, citing In re Gulack, 703 F.2d 1381 (Fed. Cir. 1983). One view of Gulack and similar cases is that they culminate in a single point, that printed material may be given patentable weight only when there is a structure-function relationship between the printed materials and the other claimed elements. See In re Lowry, 32 F.3d 1579 (Fed. Cir. 1994); In re Miller, 418 F.2d 1392 (C.C.P.A. 1969); In re Anthony, 414 F.2d 1383 (C.C.P.A. 1969). We suggest that the method of analysis set out in the Interim Guidelines directed to computer-related inventions may be incorporated into the general framework for preemption analysis, including claimed inventions directed to diagnostic methods and assays.

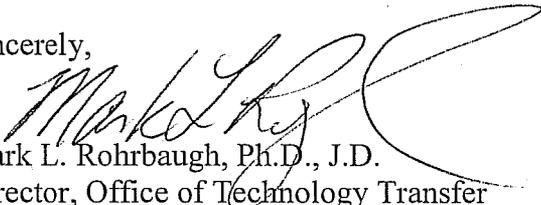
We recognize that the method of analysis presented herein, if implemented, may yield an unintended effect in that some innovators who discover a new correlation involving a Section 101 judicial exception, absent any other novel or nonobvious step, may keep such discoveries confidential. However, this is an option for any inventor, and we believe that this method of analysis will provide greater incentives to develop novel, nonobvious inventions implicating Section 101 judicial exceptions but which do not remove from the public domain what has gone before. This method strikes a balanced application of extant case law that fosters public dissemination of information, while maintaining the incentives provided by the patent system where investment of resources is needed to further develop a basic correlation between a natural phenomenon and a disease state as a commercial product or service.

We recognize that the purpose of the patent system is to foster innovation and to reward inventors for their discoveries. There is a fine balance, however, between that which is the realm of scientific inquiry alone and that which provides tangible benefit to the public. In order to provide an incentive for the latter, something more than the elucidation of a correlation between a biological phenomenon and a phenotype should be required for patentability. To be patentable, a claimed process resulting from a scientific observation should include at least one tangible novel and nonobvious step that distinguishes that which is claimed from that which came before.

In conclusion, we respectfully encourage the USPTO to consider implementing subject matter patentability guidelines, as suggested herein, that set forth a rational, objective approach to examination of claims where Section 101 judicial exceptions are implicated. It is further suggested that the USPTO consider the establishment of supplementary examination guidelines that provide guidance regarding how much weight "mental steps" should be given when making determinations regarding whether a claimed invention is novel and nonobvious.

Thank you for the opportunity to present our views. Please feel free to contact us if we can be of further assistance.

Sincerely,



Mark L. Rohrbaugh, Ph.D., J.D.
Director, Office of Technology Transfer