

CITE AS: 1 HASTINGS. SCI. AND TECH. L.J. 123

PROMETHEUS LABORATORIES V. MAYO COLLABORATIVE SERVICES

*Slip Copy, 2008 WL 878910 (S.D. Cal.), 86 U.S.P.Q.2d 1705 (March 28, 2008)*

**I. STATEMENT OF THE FACTS**

Plaintiff Prometheus Laboratories (“Prometheus”) was the exclusive licensee of two patents involving measurements of two metabolites in the blood of patients taking thiopurine drugs. According to the patents, a measurement of the levels of the metabolites may indicate the need for an adjustment in drug dosage in order to avoid toxic side effects. Defendants Mayo Collaborative Services and Mayo Clinic Rochester (“Mayo”) developed an allegedly infringing test to measure the same metabolites. Upon Mayo’s offering of their test for sale, Prometheus filed suit in the Federal District Court for the Southern District of California. After cross-motions for summary judgment, the parties jointly requested permission to submit additional briefing on two Federal Circuit decisions decided in 2007: *In re Comiskey*, 499 F.3d 1365, and *In re Nuijten*, 500 F.3d 1346.

**II. HOLDING**

The court held Prometheus’ two patents were unpatentable subject matter under 35 U.S.C. § 101. The court granted summary judgment for Mayo.

**III. REASONING**

Specifically, the court found (1) the patent claims recited a natural phenomenon and (2) the claims wholly preempted the use of that phenomenon.

The court had previously construed the claims at issue, and noted the claims disclosed three steps: the administration of the drug, determination of metabolite levels, and the warning that an adjustment in dosage might be required. The court found these three steps merely recited the correlations themselves. The court shrugged off Prometheus’ argument that the correlations could not be natural

phenomena because they would not have existed without man-made drugs. The court determined that the correlations were natural phenomena because the drugs were converted naturally by enzymes in a patient's body to form a therapeutic agent.

The court relied strongly upon Justice Breyer's dissenting opinion in the Supreme Court's certiorari denial in *Lab. Corp of Am. Holdings v. Metabolite Labs, Inc.*, 548 U.S. 124 (2006). While recognizing that the dissent was not binding precedent, the court found the reasoning persuasive. *Metabolite* involved a very similar patent on correlation of bloodstream amino acids and certain vitamin deficiencies. Justice Breyer would have granted certiorari in order to hold the claims invalid as unpatentable subject matter because they described a natural phenomenon.

The court here proceeded to find the claims wholly preempted the use of the phenomenon because anyone seeking to employ the correlation must conduct the three steps recited in the claims. It is enough, the court found, citing *Gottschalk v. Benson*, 409 U.S. 63 (1972), that the unpatentable subject matter recited in the claims has "no substantial practical application" outside the context of the claims. The court found that under *In re Comiskey*, the inclusion of a machine in the claim did not automatically make the claims patentable, citing numerous cases where the involvement of a machine did not render claims valid.

#### **IV. PREDICTION ON APPEAL**

On appeal, we predict that the Federal Circuit will reverse the court's finding of invalidity. In its recent *en banc* decision in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), the Federal Circuit held that for process claims to be patentable subject matter they must result in a physical transformation of matter or be implemented on a machine. The court also held machine implementation can protect a claim from preempting all uses of a fundamental principle. Thus, since the fundamental principle in the present case is not completely preempted, the claims will be held to be patentable subject matter. This is important because it potentially rescues any patent on a correlation that is machine implemented. This will also limit the persuasive value of Justice Breyer's dissent, at least until the Supreme Court considers the validity of patents on correlations.

TRIANTAFYLLOS TAFAS AND SMITHKLINE BEECHAM CORP. V. JON W. DUDAS

*541 F. Supp. 2d 805 (E.D. Va. 2008)*

**I. STATEMENT OF THE FACTS**

Plaintiffs Smithkline Beecham Corp. and Triantafyllos Tafas (“Plaintiffs”) and Defendants Jon Dudas and United States Patent and Trademark Office (“PTO”) filed cross-motions for summary judgment. Plaintiffs originally filed suit under the Administrative Procedure Act, (“APA”) to enjoin the PTO from enacting new rules issued by the PTO, “Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications,” 72 Fed. Reg. 46, 716-843 (Aug. 21, 2007) (“rules”), which limit, among other things, the number of continuation applications an applicant may file and the number of claims a patent may include.

**II. HOLDING**

The court granted Plaintiffs’ motions for summary judgment, holding the regulations promulgated by the PTO exceeded the PTO’s authority because they were substantive in nature.

**III. REASONING**

The court, supported by evidence of congressional intent, found that 35 U.S.C. § 2(b)(2) does not vest the PTO with “substantive rulemaking power”. The PTO has authority only to make rules related to the conduct of PTO proceedings. The fact that the PTO was required to engage in “notice and comment rulemaking” did not mean the PTO was authorized to make substantive rules. The rules in the present case were found to be substantive in nature because they affected Plaintiffs’ existing rights and obligations in connection with their patent applications. Previously, applicants had been able to file an unlimited number of requests for continued examination (RCE).<sup>1</sup> However, the new rules limited the number of RCE filings, and therefore, substantively affected Plaintiffs’ rights.

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1. Likewise, in view of precedent, there is no limit on the number of claims that could be provided in an application.

#### IV. PREDICTION ON APPEAL

On appeal, we predict that the Federal Circuit will find that the PTO rules deserve *Chevron* deference. Under *Chevron*, when Congress has not spoken upon a particular issue, courts are required to give deference to an agency's reasonable interpretation of the law. The Supreme Court has previously held that *Chevron* applies to the PTO. *See, e.g., Dickinson v. Zurko*, 527 U.S. 150 (1999). Here, the rules are procedural (i.e., not substantive) in nature because they do not refer to the validity of a patent, only to the manner in which prosecution may proceed. Moreover, it is reasonable for the PTO to limit the number of continuation applications and the number of claims. Multiple continuation applications clog the PTO, preventing examiners from adequately considering each application. Also, these limits are not absolute, because the rules allow for exceptions to these limits where the applicant can offer a reasonable justification.