

Supreme Court To Weigh Patentability Again In Mayo Case

By **Ryan Davis**

Law360, New York (June 20, 2011) -- One year after after considering the test for determining patentability in *Bilski*, the U.S. Supreme Court on Monday agreed to weigh in on the issue again in a suit over a blood test method patented by Prometheus Laboratories Inc.

The Federal Circuit has ruled twice, both before and after *Bilski* was decided, that Prometheus' method is patentable under the machine-or-transformation test. It rejected arguments by Mayo Medical Laboratories, which is seeking to market a similar method, that Prometheus was attempting to monopolize natural biological relationships.

On Monday, the Supreme Court, which ruled in *Bilski* that the machine-or-transformation test was not the sole test for determining the patentability of process claims, granted Mayo's cert petition, which argues that Prometheus' method should not be patentable.

"The Federal Circuit's ruling authorizes patents monopolizing mere observation of natural phenomena that result from carrying out steps that are part of the public's storehouse of knowledge," Mayo said in its petition. "That ruling flouts this court's precedents and the fundamental purpose of the patent laws."

The long-running case dates to 2004, when Mayo announced plans to begin using and marketing a blood test method to determine optimal dosages for drugs to treat autoimmune conditions. Prometheus then sued, claiming that Mayo's test infringed two patents.

Because the drugs are somewhat toxic, the test patented by Prometheus, which is based on the level of toxins in a patient's bloodstream, is used to ensure that the dosage level is not so high as to be dangerous but not so low that it is ineffective.

The district court ruled that Prometheus' method was unpatentable, but the Federal Circuit reversed that decision, finding that administering the drug and determining levels in the body were transformative, not merely data-gathering steps, as the lower court had held.

As such, the Federal Circuit ruled, the method was patentable under the machine-or-transformation

test, which at the time was the sole test the court used to determine patentability.

After the Supreme Court decided *Bilski*, the justices remanded the *Mayo* case to the Federal Circuit for reconsideration.

On remand, the Federal Circuit affirmed its earlier ruling, finding that because the high court did not reject the machine-or-transformation test outright, it could still be used to find Prometheus' patents valid.

In its cert petition, *Mayo* argued that the case must be reviewed because the Federal Circuit failed to abide by both the *Bilski* ruling and long-standing precedent that claims attempting to preempt all uses of natural phenomena cannot be patented.

"Prometheus has obtained an unwarranted monopoly across a broad field of medical practice. The preemptive scope of the Prometheus claims is unprecedented," *Mayo* argued. "It constitutes an embargo on research and analysis essential to the development of medical knowledge and patient care."

For its part, Prometheus maintained in its opposition brief that the Federal Circuit's ruling was clearly supported by the facts.

"The decision below is unremarkable and perfectly consistent with this court's precedent," it said. "This case is not about control over doctors' thoughts; it is about petitioners' for-profit laboratory attempting to produce and sell a multimillion-dollar competing test, the economic value of which would derive entirely from respondent's invention."

Mayer Brown LLP partner Stephen M. Shapiro, an attorney for *Mayo*, said his client was pleased that the high court decided to weigh in.

"This case is exceptionally important to the development of patent law, and to cost control and quality improvement in the field of medical services," he said.

Richard P. Bress, a partner at Latham & Watkins LLP representing Prometheus, declined to comment on the decision.

The patents-in-suit are U.S. Patent Numbers 6,355,623 and 6,680,302.

Stephen Shapiro, Timothy S. Bishop and Jeffrey W. Sarles of Mayer Brown LLP, Jonathan Singer and John Dragseth of Fish & Richardson PC, and UCLA School of Law professor Eugene Volokh represent *Mayo*.

Richard P. Bress, J. Scott Ballenger and Gabriel K. Bell of Latham & Watkins LLP represent Prometheus.

The case is *Mayo Collaborative Services v. Prometheus Laboratories Inc.*, case number 10-1150, in the U.S. Supreme Court.

--Additional reporting by Richard Vanderford. Editing by Chris Giganti.

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