Federal Circuit Finds Method of Treatment Claims Patentable Under *Bilski*

2009-09-21

On September 16, 2009, the Federal Circuit held that patent claims for a method of calibrating the proper dosage of drugs used to treat autoimmune diseases were directed to patentable subject matter because they passed the "transformation" test established in In re Bilski, 545 F.3d 943 (Fed. Cir. 2008), and did not "wholly preempt use of correlations between metabolites and efficacy or toxicity." *Prometheus Labs, Inc. v. Mayo Collaborative Servs.* The district court had granted summary judgment that the claims were invalid under Section 101. In doing so, the district court relied heavily on Justice Breyer's dissent from dismissal of certiorari in *Laboratory Corp. of America Holdings v. Metabolite Labs, Inc.* 548 U.S. 124 (2006), in which Justice Breyer said that a claim to a method for detecting a deficiency of cobalamin or folate was "invalid no matter how narrowly one reasonable interprets th[e] doctrine [that laws of nature, natural phenomena, and abstract ideas are not patentable]." *Laboratory Corp.*, 548 U.S. at 136.

The Federal Circuit decision mentioned Justice Breyer's dissent only in a footnote, saying that the "dissent is not controlling law and also involved different claims from the ones at issue here."

Most of the Prometheus patent claims required three steps: administering a

drug to a subject (i.e., a human being), determining the levels of the drug's metabolites in the subject, and a "wherein clause" requiring comparison of the measured metabolite levels to pre-determined metabolite levels to see whether more or less of the drug should be administered in the future. Some of the claims omitted the "administering" step.

In finding that the claims were directed to patentable subject matter, the Court agreed that the final "wherein" clauses are "mental steps and thus are not patent-eligible per se," but said that the mental step by itself did not detract from the patentability of the claimed method.

As for the first two steps, the Court said that the "administering" step necessarily caused the subject's body to undergo a transformation ("In fact, the transformation that occurs ... is the entire purpose of administering these drugs"), and that the "determining" step "necessarily involves a transformation, for these levels cannot be determined by mere inspection. Some form of manipulation, such as the high pressure liquid chromatography method specified in several of the dependent claims ... is necessary to extract the metabolites from a bodily sample and determine their concentration."

The Court rejected Mayo's assertion that these two steps were mere "data gathering," and concluded that "because the claims meet the machine-or-transformation test, they do not preempt a fundamental principle."

The decision in *Prometheus* may alleviate concerns that some have had about the potential effects of Justice Breyer's dissent in *Metabolite* and the Federal Circuit decision in *Bilski*. However, a number of questions remain unanswered.

The Federal Circuit opinion did not discuss how the differences between

the Prometheus patent claims and those in *Metabolite* were important. Neither did it mention *Classen Immunotherapies, Inc. v. Biogen IDEC*, 304 Fed. Appx. 866 (Fed. Cir. 2008), in which a different panel considered claims directed to methods of determining whether an immunization schedule affects the incidence of a chronic immune-mediated disorder by comparing a treatment group to a control group, and concluded that the claims were invalid under Section 101, because they "are neither 'tied to a particular machine or apparatus' nor do they 'transform[ ] a particular article into a different state or thing.'" Classen at 866 (quoting *Bilski*, 545 F.3d at 954).

Also, *Prometheus* was explicit that "this appeal does not raise any issues about lack of novelty, obviousness, or overbreadth." Accordingly, there was no apparent consideration of the potential effect of the Supreme Court's statement, in *Parker v. Flook*, 437 U.S. 584 (1978), that "[w]hether the algorithm was in fact known or unknown at the time of the claimed invention, as one of the 'basic tools of scientific and technological work,' ... it is treated as though it were a familiar part of the prior art ..." *Flook*, 437 U.S. at 591-592.

Finally, although the Federal Circuit found that both the "administering" and "determining" steps were in fact "transformative," there was no discussion of the circumstances under which the transformation should be explicitly recited in the claims.

Authors

James B. Lampert

RETIRED PARTNER

james.lampert@comcast.net

+1 617 526 6000

Colleen Superko

RETIRED PARTNER

+1 617 526 6000