Federal Circuit Finds Method of Treatment Claims Patentable

Written by Barbara A. Fiacco, Donald R. Ware, Jeremy A. Younkin

January 5, 2011

Prometheus Laboratories, Inc. v. Mayo Collaborative Services, No. 08-1403, (December 17, 2010), available here.

In the first case to consider the patentability of a life sciences invention since the U.S. Supreme Court decided *Bilski v. Kappos*, the Federal Circuit held that medical treatment claims asserted by Prometheus Laboratories were eligible for patent protection.

Prometheus's asserted claims are directed to methods for determining the optimal dosage of certain drugs, including 6-mercaptopurine ("6-MP"), which is broken down into metabolites, including 6-methylmercaptopurine ("6-MMP") and 6-thioguanine ("6-TG"). The claimed methods typically require:

- administering a drug that provides 6-TG to a subject;
- determining the levels of the drug's metabolites, 6-TG and/or 6-MMP, in the subject;
- comparing the measured metabolite levels to pre-determined levels;
- "'wherein' the measured metabolite levels 'indicate a need' to increase or decrease the level of drug to be administered so as to minimize toxicity and maximize treatment efficacy."

The district court held that the patents-in-suit were invalid under 35 U.S.C. § 101 because they claim unpatentable subject matter. Earlier, the Federal Circuit reversed on the ground that the asserted claims met the "machine-or-transformation" test, which it viewed as the definitive test for determining subject mater eligibility. The Supreme Court later held in *Bilski* that the machine-or-transformation test is not the sole test for determining patent eligibility. The Supreme Court then vacated the Federal Circuit's decision upholding the validity of Prometheus's claims and remanded for further consideration in light of *Bilski*.

The Federal Circuit's decision on remand is good news for innovators in life sciences. In its opinion, the court provided helpful guidance as to the patentability of diagnostic and therapeutic inventions:

- **Treatment claims that specifically apply a natural correlation may be patentable.** The Federal Circuit found that Prometheus's claims are directed to an application of the naturally occurring correlations between metabolite levels and efficacy or toxicity and do not wholly preempt all uses of the correlations. The Federal Circuit explained that the claims are not limited to the correlations themselves; rather, they recite specific steps for treating a specific disease by administering specific drugs and measuring metabolites. Because other drugs might instead be used to optimize the therapeutic efficacy of the claimed treatment, there was no preemption.
- **The machine-or-transformation test is still important.** While the *Bilski* Court held that the machine-or-transformation test is not the sole test for patentability, it did not disavow the test altogether. The Federal Circuit found that, as applied to Prometheus's claims, the test "leads to a clear and compelling conclusion" that the claims are patentable.
- **Method of treatment claims that involve the administration of specific drugs may be transformative.** In reaffirming its previous decision that the claimed methods meet the machine-or-transformation test, the Federal Circuit explained that the "transformation is of the human body and of its components following the administration of a specific class of drugs and the various chemical and physical changes of the drugs' metabolites that enable their concentrations to be determined." The Court rejected Mayo's argument that the claims recite natural correlations and data-gathering steps and found that the claims "are in

effect claims to methods of treatment, which are always transformative when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition."

- **Claims that require the manipulation of a sample may also be transformative.** The Court held that claims not requiring the administration of a drug also are transformative because they require determining the levels of the drug's metabolites. The Court explained that the extraction and measurement of metabolites from a bodily sample necessarily involves transformation. The Court rejected Mayo's argument that the determining step is merely data-gathering and found that the transformation that occurs during this step "is central to the purpose of the claims."
- **A claim is not invalid under § 101 simply because it includes a mental step.** The Federal Circuit recognized that the "wherein" clauses notifying physicians of the desirability of increasing or decreasing the dosage are mental steps. However, the claims are not limited to the mental steps and a "subsequent mental step does not, by itself, negate the transformative nature of the prior steps."

The Federal Circuit's decision in *Prometheus* offers hope that a variety of valuable life sciences inventions, including methods of treating, diagnosing and predicting diseases, will remain eligible for patent protection, thus encouraging innovation and providing new incentives for investment.

RELATED INDUSTRIES

- Life Sciences
- Technology

RELATED PRACTICES

- Patent Prosecution, Strategy and Management
- Intellectual Property Litigation
- Litigation
