Federal Circuit Holds That Methods for Treatment Can Constitute Patentable Subject Matter Under 35 U.S.C. § 101

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On September 16, 2009, the Federal Circuit in *Prometheus Labs., Inc. v. Mayo Collaborative Serv.*, No. 2008-1403 held that the steps of administering a drug, determining metabolite levels, and adjusting the dosage based on the those levels constitutes patentable subject matter under 35 U.S.C. § 101, and a claim directed to such a method meets the "machine-or-transformation" test set out in *In re Bilski*. Importantly, this decision holds that a drug's effect on a subject is a "transformation" sufficient to meet the requirements for patentability for methods of treatment, and that a "mental" step element in a claim does not automatically render the entire claim invalid.

In the district court ruling, rendered prior to the Federal Circuit's opinion in *Bilski*, the Southern District of California granted summary judgment of invalidity of U.S. Patents 6,355,623 and 6,680,302 under 35 U.S.C. § 101. The relevant method claims require three separate steps, namely "administering" a drug, "determining" the levels of the drug's metabolites, and comparing the measured metabolite levels to pre-determined metabolite levels to either increase or decrease the drug dosage, to minimize toxicity and maximize efficiency of treatment.

On cross motions for summary judgment, the district court found the defendant's test procedures did, in fact, infringe the patents. However, the district court later granted thedefendant's summary judgment motion that the patents were based on laws of nature, and hence the claims were drawn to non-statutory subject matter. The district court concluded the patents claimed natural phenomena—correlations between metabolite levels on the one hand and therapeutic efficiency and toxicity on the other hand—and held the "administering" and "determining" steps in the method claims were merely necessary data-gathering steps for the use of correlations. The court interpreted this to be essentially a "mental" step and therefore not patentable subject matter.

On appeal, the Federal Circuit reversed, holding the "methods of treatment claimed in the patents in suit squarely fall within the realm of patentable subject matter because they'transform an article into a different state or thing,' and this transformation is 'central to the purpose of the claimed process.'" The court characterized the machine-or-transformation test of *Bilski*, "a claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing," as creating a "two branch inquiry" where the patentee may show a process claim either is tied to a particular machine *or* transforms an article.

In this case, the Federal Circuit held the transformation "is of the human body following administration of a drug and the various chemical and physical changes of the drug's metabolites that enable their concentrations to be determined." The Federal Circuit disagreed with the district court that the asserted claims are "merely claiming natural correlations and data-gathering steps," and instead concluded they "are in effect claims to methods of treatment, which are always transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition." The Federal Circuit further held "the administering and determining steps" of the claims at issue "are transformative and are central to the claims rather than merely insignificant extra-solution activity."

Further, the Federal Circuit stated the "key issue for patentability" was "whether a claim is drawn to a fundamental principle or an application of a fundamental principle." With respect to the claimed invention in this case, the Federal Circuit held that "the inventive nature of the claimed methods stems not from preemption of all use of these natural processes, but from the application of a natural phenomenon in a series of transformative steps comprising particular methods of treatment."

The Federal Circuit did agree with the district court that the final "wherein" clauses in the claims provided for recognizing a "warning" did constitute mental steps. However, the Federal Circuit held even though those mental steps alone are not patent-eligible *per se*, they did not render the claims as a whole ineligible for patentability. The Federal Circuit noted the patent eligibility of a claim as a whole "should not be based on whether selected limitations constitute patent-eligible subject matter."

Interestingly, the Federal Circuit noted this analysis was consistent with its earlier holding in *In re Abele*, 684 F.2d 902 (CCPA 1982), which made up one part of the *Freeman-Walter-Abele Test*, the test was found to be "inadequate" for use in determining patent eligibility by the Federal Circuit in *Bilski*. In *Abele*, the

Federal Circuit held that a method claim involved the "production, detection and display" of X-ray attenuation data was not unpatentable subject matter even though it relied on an algorithm, because removal of the algorithm left all of the steps of a CAT scan in the claim. The Federal Circuit held, in this case, the presence of the mental step "similarly" does not detract from the patentability of the administering and determining steps. The Federal Circuit noted in a footnote the *Freeman-Walter-Abele* test had been superseded by *Bilski,* but stated the *Abele* portion of the analysis remained good law.

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