Federal Circuit Rules Affirmative on the Patentability of Diagnostic Methods After *Bilski*

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On December 17, 2010, the Federal Circuit issued its decision in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, __ F.3d __ (Fed. Cir. 2010) (Case no. 2008-1403) ruling favorably on the patentability of diagnostic methods to dose a medication. Pharmacology is shifting from the "blockbuster" drug model where large swaths of the population are treated uniformly to a personalized medicine model. Part and parcel of this shift is the introduction of companion diagnostics to assist in the individualized dosing of a medication. In this burgeoning market, the United States Patent and Trademark Office has issued patents for diagnostic methods and it is anticipated that there will be a wave of future patent applications for methodologies to individually dose a medication.

On June 28, 2010, the United States Supreme Court issued a decision in *Bilski v. Kappos*, 130 S. Ct. 3218 (2010), on the patentability of methods in general. The *Bilski* decision put into question whether a methodology to dose a medication would fall within statutory guidelines for patentable subject matter. The Supreme Court granted certiorari in the aforementioned case and then remanded to the Federal Circuit to consider the question in light of its decision in *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

The Federal Circuit concluded that so long as the claim does not merely involve performing clinical tests in general; but rather, a clinical test that specifically administers and/or determines the drug, then a dosing method falls within patentable subject matter. In a rare display of a court using superlative language, the Federal Circuit wrote:

> The asserted claims 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 [emphasis added.]

Further, in another strong use of judicial language, the court wrote that the machine-or-transformation test:

> "leads to a clear and compelling conclusion, *viz.*, that the present claims pass muster under § 101. They do not encompass law of nature or preempt natural correlations [emphasis added.]"

US patents 6,355,623 and 6,680,302 are method patents for optimizing the dosing of a therapeutic. The patent claims consist of either a three step or a two step method. The three step method is comprised of: (1) administering a drug; (2) determining metabolite levels and (3) being warned that a dosage adjustment may be required. The two step method is comprised of (1) determining metabolite levels in a subject who has been administered a drug and (2) being warned that a dosage adjustment dosage may be required. The patent covered Prometheus's thiopurine metabolite test for dosing 6-thioguanine to treat inflammatory bowel diseases such

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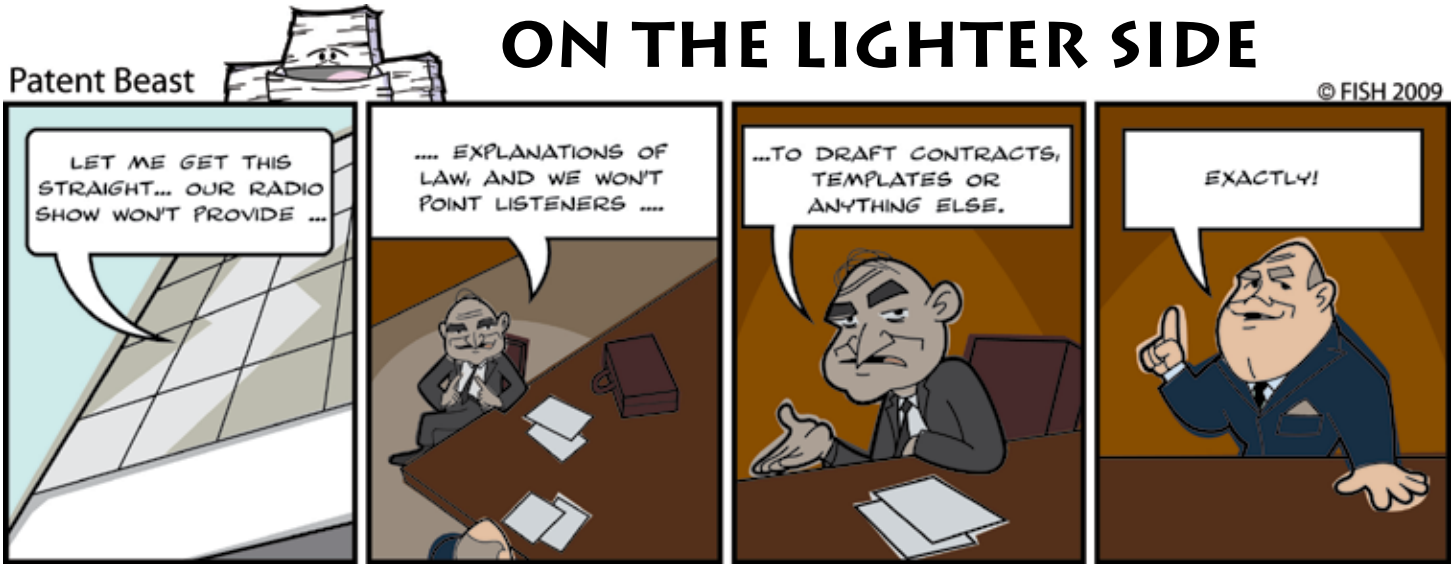

as Crohn's disease and was sold under the brand name PRO-PredictRx.

As directed by the Supreme Court, the Federal Circuit addressed whether in light of *Bilski*, *supra*, these claims are drawn to pre-empting the use of naturally occurring correlations between metabolites and efficacy/toxicity which is unpatentable or are they drawn to a specific treatment which is patentable. The Federal Circuit distilled the *Bilski* decision as not rejecting the Federal Circuits "machine or transformation test" (the transformation prong of this test which is relevant here is explained below.) "[B]ut, rather [the Supreme Court] characterized the test as 'a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under §101.'"

Having assessed the state of the law, the court began its analysis with a general observation that the claims involved administering specific drugs. Accordingly, the claims did not pre-empt the metabolite-efficacy/toxicity correlations themselves and other drugs presumably leading to the same metabolites might be administered to optimize therapeutic efficacy of a treatment. This general observation will have ramifications on the scope of equivalents to which the claim is entitled.

Next, the court got analytical and applied the transformation prong of the machine-or-transformation test to the three step method claim. Briefly, if satisfied, then the claim falls within patentable subject matter. The transformation test requires that the central to the purpose of the claimed method is transforming an article into a different state or thing. The Federal Circuit concluded that there was transformation; namely, "the transformation is of the human body and of its components following 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 moved to the two step method claim and applied the transformation test. Again, the court concluded that there was patentable subject matter. It reasoned that the step of determining metabolite levels implicitly involved the transformation of a body fluid, say blood, by high pressure liquid chromatography or other modification so as to extract metabolites for concentration determination. "The determining step, by working a chemical and physical transformation on physical substances, likewise sufficiently confines the patent monopoly …" The court's reasoning appears circumspect in that it does not mention *in situ* diagnostics requiring no separation or purification and how under this contingency there is transformation.

There is added layer of complexity. This added layer of complexity is a requirement that Federal Circuit perceives from Supreme Court precedent that after applying the transformation test, it must take a step back and decide whether the transformation is "not merely insignificant extra-solution activity." The court reasoned that "[w]hile it is true that the administering and determining steps gather useful data, it is also clear that the presence of those two steps in the claimed processes is not 'merely' for the purpose of gathering data. Instead, the administering and determining steps are part of a treatment protocol and they are transformative."

There is a certain fallacy in the court's reasoning in that it blurs a method of treatment and a method of optimizing therapeutic efficacy. In the claimed method, the central purpose for administering the drug is not to transform a human body so as to effectuate a treatment. Rather, the central purpose for administering the drug is to gather data to provide a warning.

Finally, the Court distinguished this case from *In re Grams*, 888 F.2d 835 (Fed. Cir. 1989). The court opined that the steps of the method in Grams was (1) performing clinical tests and (2) based on the data, determining if an abnormality existed. The essence of the claim was a mathematical algorithm and it was not drawn to patentable subject matter. The court distinguished *Grams* on the basis that the administering and determining steps in the present case are part of treatment regimes using thiopurine drugs.

It remains to be seen whether the Supreme will be content with the Federal Circuit's decision and if it continues to deem the question important enough for its review. At least for now, diagnostic method patents to dose a medication that involve the administration and/or determination of a drug or drug groups are patentable subject matter. In so concluding, the Federal Circuit's reason is not flawless. IPT

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