Prometheus v. Mayo: An unsurprising outcome, but a preview of the Myriad genetics case?

by

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Lourie, Rader, Bryson

The Court of Appeals for the Federal Circuit has again ruled in *Prometheus v. Mayo*, focusing on whether the "administering" and "determining" steps are transformative steps which are not "extra-solution activity." Judge Lourie wrote the opinion, which held that the claims recite patent-eligible subject matter. As you may recall, the CAFC previously reversed the District Court's holding that the claims recited non-patent-eligible subject matter, in light of its *Bilski* holding. When the Supreme Court ruled on *Bilski*, they accepted the appeal of *Prometheus*, vacated the previous CAFC decision, and remanded *Prometheus* back to the CAFC for further consideration in view of the Supreme Court *Bilski* decision.

A representative claim is as follows:

> 1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
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> (a) ***administering*** a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
>
> (b) ***determining*** the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,
>
> wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells ***indicates a need*** to increase the amount of said drug subsequently administered to said subject and
>
> wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells ***indicates a need*** to decrease the amount of said drug subsequently administered to said subject.

Another independent claim is similar, except that it only recites a "determining" step without an "administering" step. In the district court, the phrase "indicates a need" was interpreted as meaning "a warning that an adjustment in dosage may be required," rather than actually requiring the adjustment in dosage. See page 7. The district court found that the "administering" and "determining" steps were merely data-gathering steps. See page 8.

Additionally, the district court found that the correlations recited in the "wherein" steps were natural phenomena, and that the claims preempted the correlations. See page 9.

In the CAFC's previous *Prometheus* decision in 2008, it was held that ***both*** the "administering" step and the "determining" step were in fact transformative, and thus these claims passed the *Bilski* machine-or-transformation test. See pages 9-10.

In discussing this case again, the CAFC first clarifies that while a law of nature, natural phenomena or abstract idea itself cannot be patented, "an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." See page 12. The CAFC summarizes the question as follows: Are the claims drawn to a natural phenomenon which would preempt its use (like in *Benson* or *Flook*), or are the claims drawn to a particular *application* of a law of that phenomenon (like in Diehr)? See pages 12-13.

As before, the CAFC holds that both the "administering" and the "determining" steps are transformative, and that the claims recite a specific application of the laws of nature. The CAFC reiterates that the "administering" step necessarily requires a transformation, since the drug interacts with the human body, thus transforming the human body. See page 16. The CAFC also urges against confusion of transformation and laws of nature, explaining that "quite literally ever transformation of physical matter can be described as occurring according to natural processes and natural law." See page 18.

Furthermore, the CAFC again holds that the "determining" step is transformative. This is because the manner of determining the level of the metabolite *necessarily* requires a transformation of the blood sample or tissue from the human. See pages 18-19.

Next, the CAFC explains that the "administering" and "determining" steps are not only transformative, but are also central to the claims rather than being insignificant extra-solution activity. See page 19. Here, the CAFC draws a comparison with *In re Grams*. In that case, a clinical test was performed on a subject, and based on the data from that test, it was determined if an abnormality existed. However, the "essence of the claims" was regarded as being a mathematic algorithm, rather than any transformation of the tested individuals. Specifically, the claims did not require performing of clinical tests on individuals that were transformative. Rather, the tests were just to obtain data. See page 20.

Finally, as to the "wherein" clauses, the CAFC agreed that these merely recite mental steps, but stressed that the claims must be examined as a whole, rather than element-by-element. See page 21.

Overall, it is not surprising that the CAFC reached this outcome. Since the claims were regarded as passing the *Bilksi* machine-or-transformation test, it is not surprising that the claims still pass the §101 eligibility requirements after the Supreme Court clarified that the machine-or-transformation test is not the exclusive test.

However, what is interesting is whether this decision provides for a preview of how the CAFC will rule on the method claims in *AMP v. USPTO* (the Myriad genetics gene patenting case). One of the main questions will be whether phrases such as "from a tissue sample" or "from a human subject" will be interpreted such that this necessarily requires a physical transformation in order to obtain this information, similar to how the "determining" step is interpreted in this case. The other key question will be, even if this is regarded as a physically transformative step, whether this step is regarded as "extra-solution activity." It is possible that Myriad's method claims could be regarded by the CAFC as analogous to the claims in *Grams*. Therefore, it seems that this decision *might* imply a negative outcome for Myriad's method claims. Only time will tell.

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